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Part III

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40 CFR Parts 168 and 169
Final Pesticide Export Policy Statement; Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 168 and 169

[OPP–170003; FRL 4000–1]

RIN 2070–AC09

Pesticide Export Policy

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final policy statement.

SUMMARY: This document sets forth the final version of EPA's revised pesticide export policy. This policy replaces EPA's existing pesticide export policies, which were published in the **Federal Register** on May 14, 1975 and on July 28, 1980. This policy eliminates an exemption provided in the 1980 policy from the requirement to obtain a purchaser acknowledgement statement, clarifies the requirements for labeling exported pesticides, and clarifies the requirements affecting the export of research and development pesticides. EPA believes that these changes and clarifications will increase the usefulness of information on exported U.S. pesticides sent to other countries, and simplify compliance with the export requirements. The policy also discusses whether certain information about unregistered pesticides submitted to EPA will be considered confidential. Changes to EPA's program to notify countries of U.S. pesticide regulatory actions are discussed. EPA is broadening the scope of actions which will trigger international notifications, and is prioritizing the timing of transmitting these notices to other governments. The policy also presents a new system for transmittal of international notices, whereby EPA will be transmitting advance copies of the notices directly to countries and the State Department will notify the appropriate embassies.

EFFECTIVE DATE: This policy is effective April 19, 1993, except for § 168.75 which will be effective June 1, 1993.

FOR FURTHER INFORMATION CONTACT: For information about the FIFRA section 17(a) requirements regarding labeling of pesticides intended for export and procedures for exporting unregistered pesticides contact: Stephen Howie, Office of Compliance Monitoring (EN–342W), U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460 U.S.A.; telephone (703) 308–8290; facsimile (703) 308–8218.

For further information about FIFRA section 17(b) notification programs or EPA's international pesticide activities contact: Deborah Hartman, Office of Pesticide Programs (H–7501C), U.S Environmental Protection Agency, 401 M St., SW., Washington, DC 20460 U.S.A.; telephone (703) 305–7102; facsimile (703) 305–6244.

SUPPLEMENTARY INFORMATION:

Electronic Availability: This document is available as an electronic file on *The Federal Bulletin Board* at 9 a.m. on the date of publication in the **Federal Register**. By modem dial (202) 512-1387 or call (202) 512-1530 for disks or paper copies. This file is also available in Postscript, Wordperfect and ASCII.

The contents of this policy are listed in the following outline:

I. Summary

This policy discusses the requirement to obtain a purchaser acknowledgement statement for exporters of unregistered pesticides. This policy also allows certain unregistered pesticides to be exported for research and development (R&D) purposes without meeting the purchaser acknowledgement statement requirement, if the use in the country of import does not exceed the limits specified in criteria provided in this policy. Exporters are required to maintain records to substantiate claims that their products fit the exemption for R&D products.

EPA is also clarifying certain labeling requirements. Certain label statements which in the past had to be bilingual, may now be required to be multilingual, if applicable. The policy clarifies that all unregistered pesticides must have labels/labeling with the statement "Not Registered for Use in the United States of America." The policy also clarifies that research and development pesticide products must meet the labeling requirements of section 17(a)(1). The policy allows exporters to add explanatory language to use classification statements to explain the restricted status of the product.

The policy sets new procedures that exporters must follow to obtain and transmit purchaser acknowledgement statements. The final policy requires per-shipment purchaser acknowledgement statements, but also provides an alternative means for satisfying this statutory requirement. More information is required in the purchaser acknowledgement statements, and the policy also discusses new procedures for the transmittal of purchaser acknowledgement statements.

EPA's notifications to other countries about pesticide regulatory actions are discussed. The policy provides that EPA will immediately notify countries about all regulatory actions taken on the basis of health or environmental concerns, and also provide countries with an annual summary of all pesticide regulatory actions. The policy explains that EPA will directly notify countries of the actions in advance and the State Department will notify embassies.

The policy also describes EPA's projects to support environmental protection and safe pesticide use in other countries. The policy discusses the scope of EPA's international technical assistance projects to support environmental protection and safe pesticide use in other countries. The United Nations' Prior Informed Consent procedures concerning banned and severely restricted pesticides are also discussed.

II. Background

A. Statement of EPA's Goals for International Pesticide Activities

EPA has two major goals for its international pesticide activities: To ensure the safety of the U.S. food supply; and to enhance the protection of public health and the environment from unreasonable adverse effects of pesticides, both in the United States and throughout the world, by promoting the sound management and regulation of pesticides. Specifically, EPA intends to take actions:

1. To protect the American consumer from illegal residues of pesticides on imported food products by informing countries who export food to the United States of our regulatory requirements, and by working with other U.S. agencies to ensure the quality of imported food.

2. To encourage international adoption of standards consistent with sound scientific risk assessment and to coordinate U.S. approaches, to the extent permitted by U.S. law, with those of other governments and international organizations.

3. To inform other governments about U.S. pesticide regulations and to assist them in the development of their own regulatory programs so as to better protect their public's health and environment.

4. To consider the work of other governments' regulatory programs in conducting our own regulatory reviews, so that we may benefit from this work, and promote internationally consistent regulations.

B. Legal Authority

This notice sets forth EPA's final policy concerning the export of pesticide products and the notification to other countries of significant regulatory actions affecting pesticide sale and use in the United States. Section 17 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) contains the legal authority for EPA to carry out these policies. The provisions of FIFRA section 17 concerning exports of pesticides were first enacted in the Federal Environmental Pesticide Control Act of 1972, (Pub. L. 92-516) which amended FIFRA. The provisions for export notification (section 17(a)) were added in amendments to FIFRA through the Federal Pesticide Act of 1978 (Pub. L. 95-396).

An important part of section 17 is the provision of information to foreign purchasers and other governments concerning the registration status of pesticide products in the United States and EPA's conclusions regarding the safety of certain pesticide products. Section 17 of FIFRA currently mandates three systems of notification:

(1) Labeling on exported products.

(2) A notice to the foreign purchaser as well as the importing country of the export of an unregistered pesticide.

(3) A notice to all countries of certain regulatory control actions taken by EPA. Section 17 also directs EPA to participate in international efforts in pesticide research and regulation. The provisions of section 17 concerning pesticide exports are presented below.

1. *FIFRA section 17(a).* FIFRA section 17(a) provides as follows:

(a) *Pesticides and Devices Intended for Export.*-Notwithstanding any other provision of this Act, no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be deemed in violation of this Act-

(1) when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices and active ingredients used in producing pesticides shall be subject to sections 2(p), 2(q)(1)(A), (C), (D), (E), (G), and (H), 2(q)(2)(A), (B), (C) (i) and (iii), and (D), 7, and 8 of this Act; and

(2) in the case of any pesticide other than a pesticide registered under section 3 or sold under section 6(a)(1) of this Act, if prior to export, the foreign purchaser has signed a statement acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under this Act. A copy of that statement shall be transmitted to an appropriate official of the government of the importing country.

EPA interprets section 17(a) to provide authority for EPA to establish the specific requirements for labeling of exported pesticides and to establish the specific requirements and procedures for obtaining and distributing purchaser acknowledgement statements set forth in this policy.

2. *FIFRA section 17(b).* FIFRA section 17(b) provides as follows:

(b) *Cancellation Notices Furnished to Foreign Governments.*— Whenever a registration, or a cancellation or suspension of the registration of a pesticide becomes effective, or ceases to be effective, the Administrator shall transmit through the State Department notification thereof to the governments of other countries and to appropriate international agencies. Such notification shall, upon request, include all information related to the cancellation or suspension of the registration of the pesticide and information concerning other pesticides that are registered under section 3 of this Act and that could be used in lieu of such pesticide.

3. *FIFRA section 17(d).* FIFRA section 17(d) provides as follows:

(d) *Cooperation in International Efforts.*- The Administrator shall, in cooperation with the Department of State and any other appropriate Federal agency, participate and cooperate in any international efforts to develop improved pesticide research and regulations.

C. Global Pesticide Market; Exports from United States; Pesticide Usage; Agricultural Imports

EPA estimates that 4 billion pounds of conventional pesticides (measured as active ingredients) are produced and used in the world annually. (Conventional pesticides include chemicals (other than wood preservatives) produced for, and marketed primarily as pesticides: this estimate excludes sulfur, petroleum distillates, and chlorine, all of which have substantial use both as pesticides and non-pesticides.) About three-fourths of the pesticides produced world-wide (3 billion pounds) is used for agricultural purposes. The remainder (about 1 billion pounds) is used for non-agricultural purposes.

The United States, along with other industrialized countries such as Germany and the United Kingdom, is a major exporter of pesticides. In 1989, the United States exported approximately 360 million pounds of active ingredient pesticides; this figure represents approximately 28 percent of overall U.S. pesticide production, and approximately 10 percent of the total world pesticide consumption, not including wood preservatives or disinfectants. An analysis conducted by the U.S. Department of Agriculture's Economic Research Service (ERS) estimates that in 1989, total U.S. pesticide sales were $6.5 billion, of which $2.0 billion were identified as export sales. The United States is also a major importer of agricultural commodities. In general, imports comprise about 15 percent of total U.S. agricultural product consumption. For certain items--coffee, bananas and cocoa, for example — imports are a much higher percentage of the total U.S. consumption. Pesticides are used in the production and storage of many of the imported food commodities that Americans consume.

D. Reasons for Review of EPA's 1980 Export Policy

1. *Health/environmental concerns.* EPA undertook a review of its export policy at a time of growing public concern both about pesticide residues, particularly in imported foods, and also about the contribution of American-made pesticides to health and environmental problems in the developing world. EPA is concerned about food safety, the quality of the global environment and about public health around the world, and believes that it was appropriate to review its policies to see how it could better address these health and environmental concerns.

In the United States and the international community, some have expressed the view that the United States should not permit the export of pesticides that are not registered for use in the United States. This view appears to be based on the perception that pesticides which are not registered for use in the United States, and which are manufactured in the United States for export to other countries, are inherently more dangerous than those that are registered for use here.

FIFRA provides EPA with only limited authority to prohibit pesticide exports. As a matter of policy, however, the Agency's position is that banning

exports of unregistered pesticides will not necessarily solve the problems associated with pesticide use and misuse in other countries. The Agency's views in this regard have been based, in part, on the following four premises. First, controlling the export of products from the United States alone will not resolve the problems associated with pesticide use in developing countries. The United States is one of many pesticide exporters-exporting approximately 10 percent of the total world pesticide consumption. Many countries, including some developing countries, have the manufacturing capability to produce and export pesticides which have been banned or which are unregistered in the United States.

Second, EPA believes that it may be more effective to concentrate on controlling the management and use of all pesticide products, in order to reduce unnecessary exposure, rather than categorically banning certain classes of U.S. pesticides from international trade. Third, EPA's regulatory decisions are based upon risk/benefit evaluations specific to the United States. The risk/benefit balance in other countries may differ from the United States due to differences in growing conditions and pest control problems, as well as public health and environmental considerations. Thus, the fact that a pesticide is not registered in the United States may provide little indication of whether the pesticide poses a serious health or environmental threat when used in other countries. Fourth, pesticide manufacturers may not seek to register a product in the United States simply because there is no need for it here. For example, the product may control a pest that is not a problem in this country or may be used on crops not commonly grown here. For these reasons, EPA strongly supports upgrading information and technical assistance to other countries to help them make sound decisions on pesticide use and regulation.

Concern about the export of banned or unregistered pesticides has been linked to fears that food imported into the United States will contain illegal residues of pesticides which cannot be used here. This possibility has been termed the "Circle of Poison." Data gathered from residue monitoring programs, however, do not lend support to the "Circle of Poison" theory. Although the data base is not as extensive as many would like, the results of food monitoring programs show that imported foods generally do not contain either elevated levels or a large number of pesticide residues, relative to domestic food samples. Furthermore, the levels that are found do not generally present any significant public health threat. (See statistics from food import monitoring programs, discussed below.) EPA, the Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA) have several programs in place to ensure the safety of imported food. These agencies are working together to address public concerns about the "Circle of Poison" and to share information to strengthen their monitoring and enforcement programs. These programs will be discussed briefly below.

a. *FDA's programs.* Under the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA is responsible for setting tolerances (maximum permissible residue levels) for pesticides in or on food and feed crops and in processed foods. While EPA establishes these tolerances, the FDA is responsible for enforcing tolerances. Under a surveillance monitoring program, FDA samples individual lots of domestically produced and imported foods and analyzes them for pesticide residues. Using five multi-residue testing methods routinely, FDA can detect and measure about half of the pesticides with EPA tolerances, as well as others that have no tolerances, plus numerous metabolites, impurities, and alteration products of both registered and non-registered products. For those pesticides with U.S. tolerances, single residue testing methods are available to test for those residues not detected by the multi-residue methods. Single residue methods are also used for surveys for specific pesticides of concern. The analytical methods used to measure the residues are generally capable of determining levels well below tolerance values. EPA's policy is that the Agency will not grant a food use registration under FIFRA or a tolerance under FFDCA unless there is a validated analytical method for detecting and measuring residues.

The FDA imposes various sanctions on domestic and imported foods found to contain illegal residues of pesticides. Domestic foods are subject to seizure or injunction and imported foods may be detained at the port of entry when illegal residues are found. In the case of imports, "automatic detention" may also be invoked as a result of a single violative shipment. Automatic detention presumes that the violative condition may persist in subsequent shipments of the same food (same shipper or grower, same growing season). For this reason, subsequent shipments are automatically detained and required to be accompanied by a valid certificate of analysis from a private laboratory before they are allowed to enter the country.

The most recent statistics on FDA monitoring activities, which were compiled for Fiscal Year 1991 (October 1, 1990 through September 30, 1991) show that 19,082 samples were analyzed under the regulatory monitoring approach. Of these, 8466 were domestic and 10,616 were imports.

FDA collects two categories of samples-"surveillance" and "compliance" samples. Most samples gathered are surveillance samples-collected when there is no reason to suspect that a particular shipment contains illegal residues. Compliance samples are taken for follow-up when a residue problem is known or suspected.

Of the 9,933 import surveillance samples analyzed, 69% had no residues detected, less than 1% had over-tolerance residues, and 2% had residues for which there was no tolerance for that particular pesticide/commodity combination. Fruits and vegetables accounted for 78% of the import surveillance samples. Of the fruits and vegetables tested, 65% and 68% of samples, respectively, had no residues detected. Each group had less than 1% of samples with over-tolerance residues. One percent of the fruit samples and 3% of the vegetables samples had residues for which there was no tolerance. No residues were found in 90% of the milk/dairy products group, and no samples were violative.

The majority of illegal residues found result from use of a pesticide on a particular commodity for which there is no tolerance, although tolerances for residues of that pesticide may exist for other commodities. In cases where no tolerance existed, or where the residues were over the tolerance level, sanctions were imposed.

FDA acquires information on pesticide usage in countries exporting food to the United States for use in planning and conducting its pesticide monitoring activities. FDA's primary source for such data has been the Battelle World Agrochemical Data Bank, a computer data base containing foreign usage data for about 20–25 countries. The Pesticide Monitoring Improvements Act of 1988 requires FDA to negotiate with the governments of major exporting countries for pesticide usage data, with the aim of enhancing FDA's ability to direct analysis toward those residues of specific pesticides known or thought to have been used on particular commodities. Since the passage of the Pesticide Monitoring Improvements Act, FDA has expanded its coverage of imported foods sampled, testing a wider range of foods. EPA will also be able to

regularly provide FDA and USDA with information concerning which countries are receiving certain pesticides from exporters in the United States, in accordance with the provisions of EPA's Class Determination 1–91, Identity of the Importing Country, (included in today's policy), FIFRA section 17(a)(2), and the regulations governing disclosure of business information to other Federal agencies at 40 CFR 2.209. (The confidential status of information submitted to EPA in purchaser acknowledgement statements is discussed in Unit III.C. of this preamble.)

b. *USDA's programs.* Responsibility for monitoring meat and poultry exported to the United States to ensure that it is wholesome and accurately labeled, in accordance with U.S. standards, belongs to USDA. The Food Safety and Inspection Service (FSIS) of USDA implements inspection and sampling programs as required by the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act.

Federal meat and poultry inspection laws require countries exporting meat or poultry to the United States to impose inspection requirements at least equal to U.S. requirements. USDA's Foreign Programs Division evaluates foreign meat and poultry inspection programs through system reviews, including on-site reviews of plants in exporting countries. FSIS also conducts port of entry reinspection of meat and poultry products exported to the United States. Imported meat and poultry products are sampled for food chemistry and microbiological hazards as well as chemical residues (including pesticides) and drug residues. During 1990, 14,170 residue samples of imported product were analyzed for drug and chemical residues. Only 11 samples were found to contain violative levels.

2. *Congressional oversight.* In April 1989, the General Accounting Office issued a report to the Chairman of the Environment, Energy, and Natural Resources Subcommittee, Committee on Government Operations, of the U.S. House of Representatives, entitled, PESTICIDES: Export of Unregistered Pesticides is not Adequately Monitored by EPA (GAO/RCED–89–128). GAO identified problems in EPA's monitoring program regarding the section 17(a) purchaser acknowledgement statement requirement and reported that foreign countries were not being adequately notified on pesticides of concern in the United States pursuant to section 17(b). GAO recommended to the EPA Administrator that EPA take actions to strengthen its oversight of pesticide exports, including: (1) monitoring compliance with purchaser acknowledgement statement requirements; (2) changing its enforcement policy concerning the export of unregistered pesticides under section 17(a); and (3) developing criteria and procedures to improve preparation and issuance of section 17(b) notices of control actions, specifically addressing the issue of what constitutes a "significant action" involving a pesticide.

GAO was critical of an exemption to the purchaser acknowledgement statement requirement of section 17(a), established in a 1980 Policy Statement (45 FR 50274), July 28, 1980. This 1980 policy exempted exporters of unregistered pesticide products which were "similar in composition and use pattern to a federally registered product" from the purchaser acknowledgement requirements of section 17(a)(2). GAO concluded that this policy exempted the majority of pesticide exports from the notice requirement, and also concluded that the exemption made it extremely difficult for EPA to monitor compliance with section 17(a).

On May 3, 1989, the Environment, Energy, and Natural Resources Subcommittee, held a hearing on the topic of pesticide exports. In addition to the issues raised in the GAO report, the Subcommittee requested that EPA officials discuss: trends in U.S. pesticide production and exports; EPA's performance and policies relating to the implementation, monitoring, and enforcement of section 17 of FIFRA; EPA's responsibilities under the FFDCA to establish pesticide tolerances (maximum level of pesticide residue permitted on food or feed); efforts by EPA to assist FDA and USDA in the identification of potentially adulterated food imports; U.S. involvement in international discussions relating to the Prior Informed Consent (PIC) concept (57 FR 58390, December 9, 1992); and EPA's efforts to provide technical assistance to foreign countries.

EPA officials testified at the hearing that EPA's implementation of the notification procedures needed improvement and agreed to review its program and propose alternatives that would be more effective in communicating to other governments the potential risks associated with certain pesticides. EPA also indicated that it had already concluded that notification systems alone would not resolve the types of problems associated with the use of pesticides in developing countries and therefore had also allocated a portion of its limited resources to providing technical assistance to developing countries. This export policy review was initiated at the conclusion of that hearing. On February 12, 1990 (55 FR 4956), EPA published proposed policy changes entitled the Pesticide Export Policies Review and proposed amendments to the 1980 policy. The proposals discussed possible revisions to export labeling requirements, confidentiality provisions, and international pesticide notifications.

On March 28, 1990, the Committee on Agriculture, Nutrition, and Forestry, of the U.S. Senate held a hearing on pesticide exports. The Committee invited EPA to address proposed legislation, the proposed Pesticide Export Reform Act of 1990 (S. 2227), as well as EPA's February 12, 1990 export policy proposals. At the hearing, EPA officials testified in support of strengthening the provisions of FIFRA governing the export of pesticides to address growing concerns about international trade in banned and severely restricted pesticides. EPA expressed support for amending section 17 of FIFRA to enable EPA to more fully implement the prior informed consent procedure of the United Nations Food and Agriculture Organization (FAO) and Environment Programme (UNEP).

At the hearing, the February 12, 1990 proposed policy changes were discussed, along with EPA's efforts to develop education and training workshops in pesticide regulation and management for other countries, especially developing countries. EPA also stated its wish to be consistent with the international Prior Informed Consent (PIC) procedures. (See 55 FR 4962.) PIC procedures are described in more detail in Unit III.E. of this preamble. (Copies of EPA's testimony for this and subsequent Congressional hearings on the export of pesticides are included in the public record for this policy statement, as discussed in Unit V of this preamble.)

EPA believes that improvements to current law are necessary to improve or help to ensure FDA and USDA have the ability to monitor imported food for illegal pesticide residues, regardless of the origin of the pesticide. Suggestions proposed to Congress by EPA would help to ensure that unregistered pesticides have been reviewed and approved by an OECD country, and that the data supporting the approval are available to potential importing countries to assist their decision-making. While EPA supports improvements to the current law, this policy statement is based upon current FIFRA requirements.

III. Discussion of the 1980 Policy, the 1990 Proposal, Public Comments, and Responses to Comments

EPA received 40 sets of comments on its February 12, 1990 policy proposals: 18 from pesticide companies and industry, including trade associations; 2 from environmental organizations; 16 from foreign governments, 1 from a representative of the Organization for Economic Cooperation and Development (OECD); 1 from a consulting firm, and 2 from United States government agencies. The comments addressed all of the general areas of the proposed policy revisions. A brief discussion of the 1980 Export Policy, EPA's 1990 proposal, comments received and EPA's responses are presented below.

A. Section 17(a)(1)-Label and Labeling Requirements for Exported Pesticide Products

1. *Applicability of the label statement "Not Registered for Use in the United States of America" required by section 17(a)(1).* — a. *1980 policy.* EPA's 1980 policy provided that in accordance with FIFRA section 17(a)(1), all unregistered pesticides must have labels or labeling which contain the statement "Not Registered for Use in the United States of America." The statement must be conspicuous and readable. The 1980 policy also required that this statement appear in both English and the language of the importing country.

b. *1990 proposal.* EPA proposed clarifying that all unregistered products must comply with the labeling provisions of section 17(a)(1), and that all products not bearing a valid EPA registration number must state "Not Registered for Use in the United States of America" on their labels or labeling. The statement must be conspicuous and readable, and meet the requirements for multilingual labels as defined in § 168.65(b)(4) of this policy.

c. *Comments.* A number of industry representatives commented on the applicability of this requirement and ways to improve its utility. Three commentors thought that the "Not Registered for Use in the United States" labeling statement requirement did not currently apply to products which are claimed to be similar in composition and use to a U.S. registered product, and favored continuing that approach. Three other commentors also supported this approach. Two commentors suggested that EPA allow the statement to be expanded either to account for variations or to be reworded or supplemented, e.g., "this product is similar to a registered product..." The remaining commentors on this issue stated that the language "Not Registered for Use in the United States of America" should not be required on immediate product packaging since it would require relabeling in the importing country or the country of distribution. They suggested that exporters should be allowed to place this statement on the outside labeling, i.e., on the shipping or packaging containers.

d. *Response.* Section 2(q)(1)(H) of FIFRA requires that each unregistered exported product have the statement "Not Registered for Use in the United States of America" on the product label. Due to the range of interpretations expressed in the comments, EPA believes there is a need to clarify that point in this policy.

The statute prescribes that the label of an exported unregistered product must bear the statement "Not Registered for Use in the United States of America." Alternative statements which do not clearly inform the reader that the product is unregistered would not meet this requirement. EPA agrees, however, that certain additional clarifying language could improve the usefulness of this statement, since the meaning of the term "not registered" may be unclear to handlers and users of pesticides in other countries. Therefore, EPA has decided that exporters may add language to the label to explain why the product is not considered to be a registered product in the United States. For example, where a particular product is unregistered because a labeled exported use includes a crop not included in the U.S. registration, it would be acceptable to add the statement "Not registered for Use on [unregistered use crop] in the United States of America." It would also be permissible to add clarifying language after the statement "Not Registered for Use in the United States of America" such as "For research use only."

In addition, EPA would not object to language which clarifies the registration status, such as adding the statement "No Longer Registered for Use in the United States of America" or adding information regarding the reason why the registration was dropped. The labeling statement must not, however, obscure the fact that the product is not registered for use in the United States and cannot be sold for use in the United States. EPA will consider as misbranded any exported unregistered product which does not contain the basic statement "Not Registered for Use in the United States of America" or to which any added labeling language is false or misleading, as in suggesting that the product is in fact registered.

As described elsewhere in this policy, the statement "Not Registered For Use in the United States of America" may be included on the supplemental labeling, rather than on the immediate product packaging.

2. *Applicability of the labeling requirement to research and development products.*— a. *1980 policy.* The 1980 policy specifically stated that research quantities of pesticides are subject to the policy's labeling provisions.

b. *1990 proposal.* EPA proposed to clarify that the labeling requirements of section 17(a)(1) applied to all exported pesticides without exception. EPA believed that clarification was necessary to ensure that exported R&D pesticide products that are exempted from other provisions of section 17 of FIFRA still meet the labeling requirements of section 17(a)(1).

c. *Comments.* Some commentors stated that it was their understanding that research and development (R&D) pesticides were not considered to be pesticides under FIFRA, according to the provisions of 40 CFR part 172 (Experimental Use Permits), and that such substances would therefore not be subject to any FIFRA requirements including labeling. Commentors also stated that since these chemicals would be used under highly controlled conditions by highly skilled individuals there would be little need for the required labeling. Commentors noted that since these products were still in the developmental stage, many of the required statements could not be made.

Two environmental groups disagreed with the concept of exempting R&D chemicals from any labeling requirements. They believed that there should be tighter regulation of R&D chemicals because less is known about them than is known about commercial products.

d. *Response.* EPA disagrees with those commentors who stated that R&D pesticides are not pesticides regulated under FIFRA. The Agency does regulate R&D pesticides under FIFRA, even though the Agency may have determined that certain R&D pesticides would not be subject to all the requirements of FIFRA (e.g., See 40 CFR part 152).

In addition, EPA does not find any of the arguments against labeling requirements for R&D pesticides to be compelling. The minimal identity and safety information required on export labeling in section 17(a)(1), is useful in ensuring that such pesticides are properly identified during shipment and upon arrival in the importing country. The Agency believes that it is important

to treat R&D pesticides that are exported consistently with our treatment of R&D pesticides in the United States. Therefore, when R&D pesticides are exported, such R&D pesticides are subject to the FIFRA section 17(a)(1) labeling requirements described in this policy.

In addition, the Agency has determined that in order to protect confidentiality, the exporter may choose to use coded information to identify the ingredients on the labeling of exported pesticide products shipped for R&D purposes. (See 40 CFR 168.65(b)(1)(iv) of this document.)

3. *Supplemental labeling.* Under section 2(p) of FIFRA, labels are written, printed, or graphic material "on or attached to the pesticide...or any of its containers or wrappers." Labeling, including supplemental labeling, refers to labels and any written, printed, or graphic material accompanying the pesticide or device at any time or to which reference is made on the label.

a. *1980 policy.* In the 1980 policy, exporters were allowed to use supplemental labeling to meet label requirements when there were conflicts between United States and foreign label requirements. The 1980 policy provided that supplemental labeling may be attached to or accompany the product container or shipping container. The policy emphasized that the Agency intended to be as flexible as possible on this issue. Exporters were permitted to use a variety of types of labeling to comply with the requirements of FIFRA, as long as the labels or labeling, when taken together, conform to the FIFRA section 17(a)(1) requirements.

b. *1990 proposal.* EPA proposed maintaining its 1980 policy regarding supplemental labeling of exported pesticides. This policy allows the placement of label statements either on the label or on the labeling (i.e., attached material) as long as the labels and labeling, taken together, fulfill the requirements of FIFRA section 17(a)(1). EPA alternatively proposed to clarify that certain language had to appear on the immediate container unless there was a direct conflict with foreign labeling requirements.

c. *Comments.* The majority of commentors favored continuing the 1980 policy, but also indicated a need for clarification of when supplemental labeling is allowed, what may be included in supplemental labeling, and what supporting documentation may be needed to allow the Agency to ensure compliance.

While one foreign government commented in favor of continuing the existing policy, most of the comments on supplemental labeling were received from industry. All of the comments from industry representatives supported reducing the label requirements for exported pesticide products, and allowing exporters to place the majority of the required statements on attached labeling. Two commentors stated that exporters should be allowed to place all bilingual or multilingual statements on supplemental labeling, and that it should be permissible to place on immediate containers, labels only in the language of the country of intended use. One commentor stated that the policy should explicitly allow this. Two commentors stated that if the purchasing country was different from the country of final destination, the purchaser would never see the immediate containers and thus labeling in their language would be of no use. The commentors said that placing U.S.-required statements on immediate containers would simply mean that those containers would have to be relabeled at a later date.

Three commentors stated that the proposed multilingual requirement for labels (55 FR 4971) would cause problems unless supplemental labeling were generally allowed. Two cited situations where such products would have to be repackaged or reprocessed overseas before final sale and use. The other commentors mentioned that having several translations on the label would take up too much space and crowd the labels. Two commentors stated that imposing U.S. product label requirements would interfere with the ability of foreign governments to regulate pesticides. One of these commentors suggested that requiring U.S. labeling statements on exported products would insult foreign national sovereignty. The other stated that their customers were incredulous that certain FIFRA-required statements would have to be on the immediate container labels of products they purchased from U.S. manufacturers. Two commentors said that once a product is exported, EPA would not be able to enforce label provisions.

d. *Response.* The Agency continues to support the position stated in its 1980 policy statement that EPA will allow exporters to meet the labeling requirements in FIFRA by the use of supplemental labeling. By this policy, EPA makes it possible for exporters to also meet the label and labeling requirements of foreign purchasers and regulatory authorities.

EPA agrees with commentors who state that it should be permissible to label immediate containers in accordance with the requirements of the country of intended use, and to include any FIFRA required statements on supplemental labeling which must accompany shipping containers. EPA also agrees that the multilingual labeling requirements may be met through supplemental labeling. The multilingual requirement is intended to ensure that appropriate information is available to all persons who come in contact with a pesticide, and attaching that information to shipping containers will accomplish this purpose while the pesticide is being transported. This also allows the product to be labeled in a manner that is considered appropriate by the importing country.

Finally, EPA believes that it is not appropriate to require evidence that a FIFRA label actually conflicts with the labeling requirements of a foreign country in order to allow supplemental labeling. The government of a foreign country may prefer or require that the label be only in the language of their country, that the label present certain information in a specified format, or that the label conform to an accepted international label scheme.

Consequently, EPA has decided that the labeling requirements under section 17(a)(1) may be met either with a label attached to the product container or with supplemental labeling attached to the shipping containers. The supplemental labeling must be attached to the immediate product container or the shipping container at all times when it is shipped or held for shipping in the United States. For example, placing required information on the supplemental labeling of exported pesticides would be considered appropriate in the following situations: where the immediate pesticide containers are labeled to meet foreign purchaser requirements or international labeling conventions; where the producer uses supplemental labeling to meet multilingual labeling requirements; or where the producer believes there may be problems meeting the labeling requirements of foreign countries if U.S. labeling information is included on the immediate product containers. The exporter must only determine which labeling provisions are not met through information on the label attached to the immediate container and meet those requirements through supplemental labeling. Where the supplemental labeling and container labeling taken together meet the FIFRA requirements, the shipment will be considered to be in compliance with FIFRA.

4. *Expansion of Language Requirements for Labels from Bilingual to Multilingual.*— a. *1980 policy.* FIFRA

section 2(q)(1)(E) requires that "any word, statement, or other information" required pursuant to its authority must be "...in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use." EPA's 1980 policy statement interpreted this language to require bilingual statements, in English and the language of the importing country, for: (i) The warning and caution statements, (ii) the ingredient statement, (iii) where required, the word "poison" and the statement of practical treatment, and if required, (iv) the statement "Not Registered for Use in the United States of America."

The 1980 policy stated that "any language in which official government business is conducted in the country or which is the predominantly spoken language of the country is acceptable as the second language on the label." 45 FR 50275 (July 28, 1980.)

EPA's authority to establish bilingual labeling requirements for exported pesticides was affirmed by an EPA administrative law judge. See In the Matter of Shield-Brite Corporation, (Docket No. FIFRA–90–H–02, June 28, 1991).

b. *1990 Proposal.* EPA proposed to require that labeling statements, which are currently required to be bilingual, be multilingual. As such, the labeling statements would have to appear in English, in the language of the purchaser's country, and if different, in the language of the country of final destination. This was done to address those situations where a product is exported to more than one country, as well as when the country of final destination is different from the country to which it is initially exported.

c. *Comments.* EPA received a number of comments on this issue. Approximately 12 commentors supported retaining the current bilingual labeling requirements. Two environmental groups and two countries strongly supported multilingual labeling. One commentor suggested that all precautionary statements be multilingual. Nine industry commentors strongly objected to multilingual labeling as impractical, unnecessary, burdensome, and stated that it would put the United States at a competitive disadvantage. Two countries favored multilingual labeling, stating the importance of readable labels at use sites. Another country stated that it had its own strict requirements for labeling to be in its own language, but did not explain whether bilingual or multilingual label statements were permitted. One country responded that it expected labels to be in its own language.

Pesticide industry commentors expressed strong objections to this proposal and expressed a preference for bilingual labeling. Several stated that only English and the language of the country of final destination should be on the label since the intermediate country only transfers the pesticide. Other industry commentors stated that the label should be bilingual but not in the language of the country of final destination because this is often not known.

Several commentors stated that this requirement would cause problems in the case of reformulated technical active ingredients, since labeling of technical products would not be sent with the reformulated products. In addition, it is often difficult to anticipate the final destinations when technical products are shipped from the United States.

d. *Response.* EPA believes that multilingual labeling is required for the communication of important information on the safe and effective handling of pesticides. However, EPA acknowledges that there are likely to be situations where it is impractical for the U.S. exporter to know the identity of each country to which a pesticide may eventually be shipped. Therefore, an exporter must only include the language of each country to which the exporter knows, or can reasonably be expected to know, that the product will be shipped. For this reason, EPA is qualifying the requirement by adding the phrase "if known, or reasonably ascertainable" when referring to the need to include the language of the country of final destination.

Examples of when the exporter can reasonably be expected to know the destinations of a shipment, include but are not limited to the following: there is documentation in the exporter's files, e.g., sales or shipping contracts, which specify the destination of the specific shipment; an exporter's history of transactions with a particular customer would indicate where particular pesticides have been shipped and indicate where this shipment is likely to go; there is documentation in the exporter's files which indicates that a pesticide is being shipped to a country as an intermediate destination and will be reshipped to other countries for importation, in which case the other countries are considered the final destination.

EPA acknowledges that where a product is a concentrated active ingredient shipped to a foreign purchaser for reformulation, the U.S. exporter may not be able to anticipate all possible reformulations and their destination. For example, if a technical grade active ingredient is exported for reformulation into end-use products in the importing country, the exporter may not know where the end-use products will be shipped. In this case, the exporter would only be required to label the product in English, and the language of the importing country. Note, however, that if the exporter knows, or can be reasonably expected to know, that the active ingredient is being shipped to an intermediary who will ship it to another country where reformulation would take place, multilingual labeling would be required in English, in the language of the country of the intermediary, and in the language of the country of the reformulator, who is considered to be the final destination.

Although EPA believes that multilingual labeling will help to communicate more information to people who come into contact with pesticides during shipment, handling, and use, EPA also recognizes that there are limitations to the usefulness of multilingual labeling. Some users of pesticides may not be able to read, and for those people, pictures or symbols may be more effective in conveying use and safety information. As such, EPA has reviewed and strongly supports the Guidelines on Good Labeling Practice developed by the Food and Agriculture Organization of the United Nations, March 1985. These guidelines were prepared with the intention of assisting people who prepare pesticide labels, in communicating the essential elements of the safe and effective use of pesticides to end-users.

The FAO guidelines recommend communicating information on hazard by using the pictorial representations indicating toxicity, flammability, explosiveness, oxidation, irritancy, and corrosiveness. In addition, international symbols used to indicate various physical properties have been combined with short hazard classification statements, used in the World Health Organization (WHO) Hazard Classification System. WHO's hazard classification is based on the hazard presented by the formulated product (e.g., a WHO Class Ia pesticide active ingredient could be in Class II when formulated.)

The guidelines also recommend using color coding, based on the toxicity of the product, and should be linked to the WHO Recommended Classification of Pesticides by Hazard. The FAO guidance suggests placing a band at the bottom of the label, occupying not less than 15% of the label area, in the

appropriate color for the hazard classification. For pesticides which fall into the WHO Class Ia or Ib, red is recommended. Pesticides which are classified as WHO Class II should have a yellow band, and pesticides in WHO Class III, a blue band. Pesticides in WHO Class III which are technical products unlikely to present hazard in normal use (Table 5 of WHO classification Guidance), should have a green band.

EPA is considering whether to also require the WHO hazard classification, along with the appropriate color code and pictograms, on the label or labeling of pesticides for export. This issue may be addressed in a future **Federal Register**.

Producers of pesticide products for export are reminded that they may label products according to WHO guidelines in order to meet the requirements of foreign purchasers, as long as the labeling requirements of section 17(a)(1) as described in this policy are met. If necessary, supplemental labeling as described in this policy may be used in order to meet the labeling requirements of section 17(a)(1) when immediate containers are labeled in accordance with WHO guidelines.

5. *Modification of the use classification statements.*— a. *1980 policy.* FIFRA section 2(q)(2) requires that pesticide product labels contain a statement of the use classification under which the product is registered. The 1980 policy stated that the use classification must appear on the labeling of the pesticide; e.g., for restricted use pesticides, the statement "Restricted Use Pesticide" must appear on the label or labeling. However, summary statements regarding the terms of the restriction, e.g., "For retail sale to and application only by Certified Applicators..." were not required.

b. *1990 proposal.* EPA did not propose any changes to the use classification statement labeling requirement.

c. *Comments.* A number of commentors requested clarification of what information EPA might allow to explain use classification statements to make them more understandable in other countries. Several commentors both from industry and environmental groups stated that terminology normally included in the use classification statement of products registered in the United States would be confusing to importing countries. Some commentors stated that the term "restricted use pesticide" might be confused with the UNEP/FAO term "severely restricted" which has a different meaning from "restricted use pesticide" under FIFRA. A suggested modification was that EPA allow the exporter to include the terms of the restriction with this statement.

d. *Response.* In the 1960 policy statement, EPA stated that all of the conditions applicable to a use classification need not be listed on the labeling. EPA believed that such conditions may not have much meaning outside of the United States. For example, the statement "For retail sale to and use only by Certified Applicators..." would have little meaning to someone not familiar with U.S. pesticide regulations. The comments EPA received suggested that even the basic terms used in use classifications (e.g., "restricted use pesticide"can result in confusion. Therefore, EPA agrees that some clarifications should be allowed, as long as they do not obscure the classification statement. Thus, it is permissible to add explanatory language which accurately explains the meaning of a use classification. For example, the statement "restricted use pesticide" may be expanded to read: "Restricted in the United States of America to use by certified applicators" or "Restricted Use Pesticide. In the United States this product is restricted to use by applicators determined by each state to be competent in pesticide application, and human health and environmental consequences of misuse." Note, however, that if such explanatory language falsely represents or is misleading regarding the use classification in the United States, the product will be considered misbranded. EPA also wishes to point out that a use classification should only be listed if one has been assigned pursuant to the U.S. registration.

6. *Identities of parties required on the label.* The 1990 proposal provided guidance on elements which must appear on the label or labeling of each exported product (55 FR 4971, February 12, 1990.) Under "Identity of Parties," the proposal read: "Name and address of the producer, registrant (if any), and the person for whom the pesticide was produced, must appear in the labeling." This sentence should have read "Name and address of the producer, registrant (if any), or the person for whom the pesticide was produced must appear in the labeling." The correct language is being used in the final policy.

B. FIFRA Section 17(a)(2)-Procedures for Exporting Unregistered Pesticides—Purchaser Acknowledgement Statements

1. *Similar in composition and use exemption.* — a. *1980 policy.* The 1980 policy created an exemption from the requirement to obtain a purchaser acknowledgement statement for unregistered pesticides which were minor variations on formulations registered in the United States, which contained only active ingredients registered in the United States, and which had similar use patterns to U.S. registered products. To be considered similar to a U.S. registered product in composition and use pattern, a pesticide product had to contain the same active ingredient or combination of active ingredients, and be in the same category of toxicity as a federally registered product. The use pattern also had to be similar to the use pattern of the federally registered product to which it was being compared.

b. *1990 proposal.* EPA proposed to modify or to eliminate the existing exemption from the purchaser acknowledgement requirement for products substantially similar in composition and use to currently registered products. If the exemption were retained, EPA proposed that the burden of substantiating the claim remain with the exporter, and that any similarity claims be supported by documentation. The Agency was also considering whether such documentation should be maintained in records which would be made available to EPA upon request, or whether the documentation should be submitted to the Agency.

c. *Comments.* Two environmental groups advocated eliminating the exemption, citing the ambiguity of the exemption criteria, the burden of proving compliance with whatever criteria might be adopted, and the opinion that the exemption appears to be a "loophole" for unregistered products. The commentors suggested that the regulated community should not decide which products did and did not require notification. One foreign government also supported eliminating the exemption due to the ambiguity of the exemption criteria. One industry commentor stated that the exemption created problems for the regulated community and stated that if the exemption were retained, it must be better defined.

One foreign government and an OECD representative supported keeping the exemption to preserve the utility of notices sent to foreign governments. However, they expressed enforcement concerns if the exemption is maintained, since they felt that it would be difficult to ensure that the exemption is properly used.

Most of the industry commentors were in favor of maintaining the exemption. Several of these commentors

said that removal of the exemption would result in increased burden but they did not elaborate beyond the estimates EPA published in its proposed policy. In addition, some commentors believed that eliminating the exemption would result in potential trade disadvantages since foreign firms would not be required by their governments to obtain such notifications. Several stated that they did not perceive any potential benefits from the elimination of the exemption.

Proponents of the exemption cited instances where products, which are otherwise identical to U.S. registered pesticides, would be subject to notification as "unregistered" because of: (1) Relabeling or repackaging to conform with metric weight formulations, including possible rounding-off differences resulting in slightly different technical active or inert concentrations; (2) minor inert modifications including color or odor modifications to meet customer specifications; and (3) labeling for uses for which there are no U.S. applications such as for certain tropical crops. Some commentors pointed out that in these cases the relevant safety data which would apply to registered pesticides are just as applicable to the unregistered "similar" products. It was stated that custom blending to meet foreign formulation requirements would often result in products that are not identical to the U.S. product, although the product is otherwise the same.

Many proponents of the exemption stated that a clearer definition of "similar" was needed. Several asked that explicit criteria be made available. One stated that EPA needed to propose such a clarification for public comment. Most commentors from industry did not object to the proposal that exporters maintain records to substantiate similarity claims, but many objected to a reporting requirement.

d. *Response.* EPA has concluded that the exemption should be eliminated. As was pointed out by some commentors, the exemption creates compliance problems for industry and has also proven to be difficult for the Agency to enforce. EPA believes that elimination of the exemption is the best way to resolve the difficulties associated with compliance, both for the regulated community and for EPA. In addition, the Agency believes that elimination of the exemption will provide the importing countries with better information on pesticides exported from the United States.

At the time that EPA published the proposed policy it believed that compliance and enforcement problems could be partially solved by clarifying that the burden of proof lies with the person asserting similarity. However, even with such provisions, including requiring the exporter to substantiate claims of similarity, EPA has determined that arriving at consistent interpretations would still be extremely burdensome for the Agency, and confusing to the regulated community and other governments.

In the proposed policy, EPA expressed concern about whether eliminating the exemption would raise problems in terms of increased burden on exporters and the governments of countries receiving the purchaser acknowledgement statements in terms of the number of notices that may be required. EPA explicitly requested comments on this issue, including any potential benefits to importing countries. While several commentors mentioned increased burden, none provided information beyond the estimates presented by EPA. Those burden estimates were small and not judged to be important enough to offset the compliance and clarity problems associated with the exemption. EPA believes that only a small number of additional notices would be required annually, and the burden imposed by each notice is not large. EPA does not, therefore, find the arguments based on increased burden on exporters to be compelling.

EPA was concerned that eliminating the exemption might detract from the usefulness of the purchaser acknowledgements statements to receiving governments. Since transmittals of statements to foreign governments will be made by EPA, (See discussion of EPA's transmittal of section 17(a) notices, in Unit III.B.6. of this preamble) the Agency intends to continue to review its internal procedures to determine if there are ways to increase the usefulness of the statements to other governments, and to make them easier to process. For example, EPA is considering attaching a revised cover sheet, with more detailed information than the one currently used, which would explain the purpose of the purchaser acknowledgement statements to help countries distinguish them from other international notifications, such as section 17(b) and PIC notices. EPA may also specially identify statements which the Agency has reason to believe may be of specific interest to importing countries, such as statements associated with chemicals which are identified on international lists as posing special concerns. EPA believes that such steps may largely offset any potential burden or loss of utility to other governments that could otherwise result from elimination of the exemption.

For the purposes of FIFRA section 17(a), EPA will consider products to be registered if they are registered under section 3 of FIFRA, or if they were once registered and are being sold under section 6(a)(1) of FIFRA. Except as discussed in this policy, any variations in the formula of the export product from the formula of the U.S. registered product, or any uses or claims on the export product's label which are not consistent with the uses or claims stated on the label of the U.S. registered product, render the export product "unregistered" and subject to all the requirements for exporting an unregistered product pursuant to FIFRA section 17(a). As discussed later in this section, certain modifications to the labeling, packaging, or composition will not cause an otherwise registered product produced solely for export to be considered unregistered.

Applications for pesticide registrations under FIFRA must be accompanied by a copy of the product's proposed labeling, including uses and claims, and a full description of tests made and results thereof in support of such claims. A pesticide's formulation, uses and claims which are stated on its labeling are all essential components of the pesticide's U.S. registration. EPA believes that the product labeling is an important reference point for determining whether or not any pesticide product, including one produced for export, is registered in the United States. EPA's pesticide labeling regulations specifically require that an approved product label must be attached to the immediate pesticide product container. This is to ensure that the label information is transmitted and understood under customary conditions of sale and use.

EPA understands that when pesticide products are exported, it may not be practical to label the immediate container with the U.S. label without defeating the packaging or labeling needs of the foreign purchaser. For example, the purchaser may need to label the product container with a label meeting the requirements of the country of import. Although EPA believes that the labeling is critical in identifying a product as registered, it is not EPA's intent to consider exported products unregistered simply for failing to attach the U.S. approved label to the immediate product container. Therefore, EPA will allow registered products to still be considered registered for the purposes of this policy when the labeling approved under the U.S. registration is not directly attached to

the immediate product container, as long as that labeling accompanies the product at all times, i.e., as supplemental labeling. If an exported product does not bear the FIFRA section 3 labeling either on the immediate product container or as supplemental labeling, it will not be considered registered for the purposes of this policy. The sale or distribution of such a product without meeting the acknowledgement statement requirements of section 17(a)(2) will constitute the sale and distribution of an unregistered pesticide in violation of FIFRA section 12(a). (Note: section 2(q)(1)(C) of FIFRA precludes any person from exporting a product that is in imitation of, or is offered for sale under the name of, another pesticide. This means that a person cannot use the pesticide product labeling approved under another person's registration in order to export their own product as a "registered" product.)

When a product is claimed to be a registered product, and is accompanied with the approved U.S. labeling, any labeling material which is in addition to the U.S. label (as would be the case when the immediate container is labeled in accordance with foreign purchaser specifications) must be compatible with the U.S. labeling. Except as discussed in this policy, if the product labeling indicates a different formulation from the registered product, or states new uses or claims, the product will be considered to be a different product and not registered under FIFRA. The presence of contradictory labeling statements associated with the same product will also render that product misbranded.

Export product labeling that states information concerning composition, claims or uses which are within the scope allowed by the U.S. label will not be considered to be in conflict with the U.S. label. For example, if the export label of a U.S. registered product lists some, but not all, of the U.S. registered uses or crop applications, the registration status for purposes of this policy would not be affected. Similarly, if the export product label states application rates that are allowed under FIFRA when the registered product is used in the United States, the product would still be considered registered.

If the export labeling states application rates in metric units, the product's regulatory status will not change if the metric measurements are an accurate conversion from the U.S. units. An exporter of a U.S. registered pesticide may add new uses to the label of that product for export purposes, without triggering the requirements of section 17(a)(2), as long as the new uses are within the same general use patterns as those for the registered product. (Pesticide use patterns are listed in Appendix A to part 158-Data Requirements for Registration: Use Pattern Index. The general pesticide use patterns are: terrestrial food crop and terrestrial nonfood crop; greenhouse food crop and greenhouse nonfood crop; aquatic food crop and aquatic nonfood crop; indoor use; and forestry use.) Adding new uses to the label which change the use pattern, such as changes from non-food to food use, outdoor to indoor use, or terrestrial to aquatic use, render the product unregistered and subject to the requirements of section 17 for unregistered products. If the new use added to the label is a food or feed use, a tolerance must already be established for the use of that pesticide in or on that commodity or the product will be considered unregistered and subject to the requirements of section 17(a)(2).

If the export product label contains statements regarding the formulation or composition of the product which differ from that allowable under the U.S. registration (i.e. statements that differ from the statement of ingredients listed in the certified statement of formula), the product will be considered unregistered. For example, EPA will consider any stated concentrations of any active ingredients which fall outside the certified limits for that product to render that product unregistered. EPA will also consider the product to be unregistered when the label statements indicate the presence of active or inert ingredients which are not in the U.S. registered product, or when the label does not list active or inert ingredients which are in the U.S. registered product. EPA may determine such products to be misbranded and adulterated. EPA wishes to emphasize that except as provided in this policy, any differences in formulation or composition between the exported product and that indicated in the confidential statement of formula for the registered product, including inert ingredients, will cause the exported product to be considered unregistered. In addition, any differences in formula or composition must be reflected in records which show the complete formula of the export product, in accordance with the requirements of 40 CFR 169.2 and this policy.

EPA recognizes that certain modifications to the composition of an export product should not render the export product "unregistered" and thus subject to the requirements of FIFRA section 17(a)(2). Therefore, EPA has decided that a change in the color or fragrance of the export product will not affect the product's registration status, as long as certain conditions are met. The change in color must result only from the addition of a dye included on the list of the chemicals exempted from the requirement of a tolerance at 40 CFR 180.1001, and the dye must not be a List 1 inert. (List 1 inerts are those inerts which the Agency has identified as presenting toxicological concerns. The classification of inerts is explained in EPA's Policy Statement on Inert Ingredients in Pesticide Products, 52 FR 13305, April 22, 1987.) The change in fragrance must result only from the addition of a chemical included on the list of chemicals exempted from the requirement of a tolerance (40 CFR 180.1001) and the added chemial must not be a List 1 inert. In addition, the change in fragrance must not result in a pesticide product containing a food or food-like fragrance. (See "Food Fragrances in Pesticide Formulations," EPA's Office of Pesticide Programs Policy and Criteria Notice number 2155.1, November 20, 1975.)

EPA also recognizes that there are instances where a company may need to slightly modify the composition of one of its U.S. registered products for export purposes. EPA will not consider a company's modification of its registered product to render that product "unregistered" in the following situation. An exporter, who is also the registrant and/or manufacturer of a U.S. registered pesticide, (other than pesticide products intended for public health uses which are required or conditionally required to submit efficacy data pursuant to section 158.640), may decrease the percentage of the active ingredient(s) of that product by adding a List 4 inert ingredient, without causing that product to be considered "unregistered" and triggering the requirement to obtain a purchaser acknowledgement statement. In EPA's Policy Statement on Inert Ingredients in Pesticide Products, EPA included inert ingredients on List 4-a list of inert ingredients posing minimal hazard or risk-if the inert ingredients were generally regarded as innocuous. (52 FR 13305, April 22, 1987.)

Such limited modifications may only be made by the registrant and/or the manufacturer of the U.S. registered product. As discussed above, EPA's 1980 Pesticide Export Policy exempted exporters of unregistered pesticide products from the purchaser acknowledgement statement requirement for products which the exporter claimed were "similar in composition and use pattern to a federally registered product." EPA has

concluded that only the registrant and/or the manufacturer of the product may be able to legitimately claim that its export product is the same composition as its own federally registered product, except for the addition of List 4 inert ingredients. EPA has concluded this because only the registrant and/or manufacturer have access to the product's confidential statement of formula thereby making it possible for them to know the extent to which the modified product differs from the registered product. Pesticide exporters are no longer permitted to claim that their product is similar to another company's registered product and thereby exempt themselves from the purchaser acknowledgement statement requirement.

EPA's pesticide registration regulations also provide that certain changes may be made to a product's composition, labeling or packaging, without notification to or approval by the Agency. (See 40 CFR 152.46(b)). These changes include any changes in package size and label net contents, provided no change in use directions or requirement for child-resistant packaging would be necessary for the product to be registered for use in the United States. For example, if child-resistant packaging is required for a particular pesticide product in the United States, and the product will be exported without child-resistant packaging, the product would be considered unregistered and therefore subject to all the requirements of FIFRA section 17(a), including the requirement for a purchaser acknowledgement statement.

If an exporter needed to repackage a product in a size to meet a foreign purchaser's specifications, that modification would not affect the registration status of the export product. Other modifications to the label used for export purposes which will not affect the export product's registration status are: the use of metric units for net contents, dosages, and other numeric expressions; the use of a different format for the label, provided that the information does not contradict the U.S. label; revision of non-mandatory U.S. label statements, consistent with 40 CFR part 156, including additions or changes required by other Federal statutes or regulations; a change of the name or address of the registrant, except for a change resulting from transfer of ownership, which requires that a registrant keep his name and address current with the Agency; and any correction of typographical or printing errors that appeared on the U.S. labeling. (See 40 CFR 152.46(b)).

Finally, EPA recognizes that there may be situations where minor discrepancies between an export label and the U.S. registered label result from the translation of statements or the conversion of units. Where such differences are not significant, EPA does not believe that they should affect the registration status of the product for purposes of export. However, except as provided in this policy, differences which indicate new uses or claims would be considered to be significant and to render the product unregistered. EPA wishes to emphasize particularly that warning or cautionary statements that translate to a lower level of warning or caution than that indicated on the U.S. labeling will be considered to be significantly different.

EPA believes that in addition to the flexibility discussed above, this policy will provide importing countries with clearer, more accurate information on the registration status of the pesticides being exported from the United States, consistent with the requirements of the statute.

2. *EPA treatment of exports of unregistered pesticides for research purposes.* — a. *1980 policy.* The 1980 policy stated that experimental use products will be considered unregistered, therefore requiring signed purchaser acknowledgement statements prior to export. However, small amounts of pesticides exported only for research purposes would be considered exempt from the purchaser acknowledgement statement requirement.

b. *1990 proposal.* EPA proposed that pesticide products exported solely for research purposes would not be considered to be in violation if no purchaser acknowledgement statement was sent if the exporter met certain recordkeeping requirements to substantiate the claim that a product is shipped for research purposes. In addition, EPA proposed that the exporter should bear the burden of demonstrating that the pesticide qualifies for the research exemption.

c. *Comments.* Two environmental groups stated that research and development (R&D) products should not be exempt from the requirements of section 17(a)(2). They stated that such products constitute "unknowns" and that consequently it is very important that foreign governments be aware of their importation. Other commentors stated that R&D chemicals tended to be small quantities which would not cause great potential health or environmental risks.

One industry commentor stated that it would be simpler to obtain the purchaser acknowledgement statement than to substantiate R&D use abroad, and consequently supported eliminating the exemption. However, all other industry commentors who addressed this issue stated that the exemption should be maintained, and that export for small scale R&D use could be substantiated. Several supporters of the exemption mentioned that requiring purchaser acknowledgement statements where R&D chemicals are being exported for testing, would provide the locations of potential markets to their competitors, and cause a company competitive harm. Several commentors stated that it was their belief that R&D pesticides were not "pesticides" under the meaning of FIFRA, as stated at 40 CFR 172.3, and hence were exempt from any of the requirements of section 17 including both labeling and acknowledgement statements. (See discussion in Unit III.A.2.d. of this preamble.) Some commentors stated that they did not believe that there was a great need for notification of other governments of R&D exports because R&D products are used in tightly controlled situations by highly qualified persons. They did not believe that there was a significant chance for misuse or other risks.

Finally, some commentors were concerned that if there is no exemption for the export of R&D products, particularly if notices are made publicly available, product confidentiality could be jeopardized. These commentors pointed out that proprietary knowledge is treated differently in some foreign countries than it is in the United States. Therefore disclosure of the identity of research products carries a much greater risk of competitive harm internationally than would be the case in the United States.

d. *Response.* As discussed earlier, EPA disagrees with the commentors who stated that exported R&D pesticides are not considered to be pesticides under FIFRA. Research pesticidal products are considered to be pesticides regulated under FIFRA, unless EPA makes determinations otherwise that are applicable to the specific products in question.

EPA does, however, believe that under many research conditions involving small quantities, R&D pesticides will be used in a manner that renders the risk of potential adverse effects to human health or the environment negligible.

EPA acknowledges the concerns that some commentors had regarding the export of "unknown" pesticides to countries without their governments having the benefit of purchaser acknowledgement statements. EPA

believes that governments should be notified when there are large-scale research and development applications or applications where there is a strong potential for direct human or dietary exposure. For the reasons stated above, however, EPA does not believe that it is useful to impose this requirement in the case where only small scale controlled uses are intended.

Consequently, EPA will not consider exports of R&D pesticides intended for small-scale research application (as defined below) to be in violation of section 17(a)(2) if no purchaser acknowledgement statement was sent. EPA believes that it is critical to define what is meant by small-scale research applications and is addressing this issue in this policy.

3. *Definition of small-scale research application.* —a. *1980 policy.* The 1980 policy did not include any specific definition of small-scale research product application.

b. *1990 proposal.* EPA proposed to provide specific criteria to define when an R&D export would not be considered to be in violation of the purchaser acknowledgement requirements of section 17(a)(2) of FIFRA. These criteria were based on the scope of the application and other factors relating to possible human contact or dietary exposure rather than on the physical quantity involved since the actual amounts of pesticide could vary considerably based on type of pesticide, concentration, and other factors. Exports of pesticides for research purposes in quantities that would not normally require notification of EPA and issuance of an experimental use permit if the use were in the United States, would not be considered to be subject to the purchaser acknowledgement requirement of section 17(a)(2).

c. *Comments.* One foreign government and several industry commentors expressed general approval of EPA's proposed criteria for defining small-scale R&D quantities based on use, although one of the commentors suggested that a closer adherence to the criteria cited at 40 CFR 172.3 should be used. Another stated that there needed to be some further clarification of what was intended in the criteria, i.e., that the limits on proposed use be on a "per-country" rather than a "per-pesticide" basis.

One commentor suggested that it was not appropriate to use the proposed criteria. The commentor stated that these criteria were designed for the United States, and only accurately define research applications in the United States. They would not, therefore, necessarily be applicable worldwide.

d. *Response.* EPA acknowledges that the regulation of R&D pesticides may vary in different countries, but believes that the advantages of using a single set of criteria that are consistent with those in place for similar testing of R&D pesticides in the United States outweigh any disadvantages. The Agency did not wish to use significantly different criteria from those used in the United States unless there were compelling reasons to do so.

EPA agrees that it is necessary to clarify how to interpret these criteria when there are multiple shipments to multiple countries. EPA believes that the most consistent approach is to consider separately product shipments within a calendar year to multiple countries. If the R&D use of the product shipped within a given calendar year by an exporter to a particular country exceeds the criteria stated in this policy, EPA will consider failure to submit a purchaser acknowledgement statement to be a violation of section 17(a)(2). For example, if within a calendar year, an exporter is shipping a pesticide for research purposes, and the product may be used on more than 10 acres (4.05 hectares) within the country of import, EPA would consider failure to submit purchaser acknowledgment statements regarding those shipments to be violations of section 17(a)(2). If a shipment, or series of shipments over the course of a calendar year to a foreign purchaser for R&D use in one country meets the criteria outlined above, separate shipments to other countries would be considered separately.

The comments generally favored the proposed criteria, and EPA is therefore including the proposed criteria in the final policy. EPA is clarifying that these criteria concern only the acknowledgement requirements and are not pertinent to other FIFRA requirements, such as labeling required under section 17(a)(1).

4. *Substantiation and/or verification of small-scale R&D exports.* — a. *1980 policy.* The 1980 policy did not include any specific criteria for defining small-scale pesticide export for research purposes only.

b. *1990 Proposal.* EPA proposed that records substantiating claims for small-scale R&D pesticide exports be retained for 3 years and be available for inspection, or, alternatively, that information substantiating such claims be submitted to the Agency.

c. *Comments.* Several commentors stated a strong preference for a recordkeeping requirement rather than any new reporting requirements. One commentor stated that reporting on a case-by-case basis could be acceptable. Another commentor stated that the small quantities of R&D shipments would in themselves indicate the R&D nature of the intended use.

d. Response. Since EPA has limited ability to review actual use once pesticides are exported, the Agency must rely on records substantiating the intended use. EPA may determine that any shipment or series of shipments of an unregistered pesticide, for which small-scale R&D purposes cannot be substantiated, is in violation of the requirements of section 17(a)(2).

EPA believes that examination of appropriate records will be adequate to determine whether small-scale R&D criteria are met. Records to support claims of this nature must contain at least the following information: (1) identify the product and quantity shipped in a given year to a given purchaser in a specified county; (2) include a detailed description of use patterns (i.e., application rates, sites, dosages, etc.) which are consistent with the premise that the shipped quantity would be used within the R&D criteria; and (3) contain confirmation, such as signed statements from the purchaser, letters of transmittal, etc., which indicates that the shipment(s) of the product were to be used for R&D purposes consistent with the quantity shipped and the described uses. EPA does not believe that records which only show the quantity of product shipped are sufficient for substantiating R&D intent, since a quantity that would qualify as "research" for one type of product or use may represent a commercial-sized quantity for a different product or use.

EPA has reconsidered the proposed 3-year duration for record retention and instead is requiring that the records must be retained for the period specified at 40 CFR 169.2(h). This is being done to be consistent with other recordkeeping requirements for these products. At the time of publication of this notice, this period is 2 years.

5. *Timing of Purchaser Acknowledgement Statements.* — a. *1980 policy.* Section 17(a)(2) requires that before exporting a pesticide which is not registered for use in the United States, the purchaser must acknowledge in writing its understanding that the product is not registered for use in the United States and cannot be sold in the United States.

Under EPA's existing policy, an exporter of an unregistered product must have a copy of the signed statement prior to the export of the first shipment each year of an unregistered

product to a particular purchaser for each country.

b. *1990 proposal.* In the 1990 proposal, EPA stated that it was examining its policy of requiring annual submissions of the purchaser acknowledgement statement. EPA proposed maintaining the current system of annual submissions, as described above, but also requested comment on the option of requiring purchaser acknowledgement statements for each shipment.

c. *Comments.* Twelve commentors strongly supported maintaining the current system. Most commentors believed that the current system of annual submissions should be continued. They contended that per-shipment notification would create a large paperwork burden, delays in shipment, and trade disadvantages. One foreign government commented that annual submissions would meet their needs.

One commentor supported per-shipment notifications, or alternatively, the requirement of a detailed annual summary, specifying the quantity shipped and the dates, to show the flow of shipments over the entire year. The commentor suggested that EPA could require the information to be provided at the beginning of the year's shipments and updated if anticipated shipments deviate from the initial projections. The commentor stated that such a notification system has worked reasonably well under the hazardous waste export program pursuant to the Resource, Conservation and Recovery Act (RCRA), and has the significant additional benefit of providing much more useful information to other governments, U.S. agencies, and the public.

Another commentor requested that EPA require exporters to submit the signed statements to EPA within 10 working days of receipt or prior to the first shipment, not within 7 days of receipt as currently required.

d. *Response.* EPA has decided that purchaser acknowledgement statements must be submitted on a per-shipment basis unless the exporter complies with all of the provisions of an alternative approach as provided in this policy. The alternative approach requires the exporter to obtain a purchaser acknowledgement statement prior to the first shipment of each unregistered pesticide to a particular purchaser in a foreign country, and to submit to EPA an annual summary of all shipments of that product to that purchaser.

EPA believes that the Congressional intent underlying the purchaser acknowledgement statement requirement was that countries receive information concerning each shipment of unregistered pesticides to their country. Section 17(a)(2) requires that the foreign purchaser sign a statement acknowledging awareness of the registration status of the product and that the exporter submit this statement to EPA prior to export of an unregistered pesticide. Since section 17(a)(2) specifies that no unregistered pesticide shall be exported without a signed purchaser acknowledgement statement, it is EPA's interpretation that this section requires that there be a purchaser acknowledgement statement for every shipment.

At one time, EPA believed that annual submission of a notice for the first shipment in the calendar year to each purchaser in each country was adequate to meet this requirement, because it would provide regular notification to foreign governments. In the 1980 policy, EPA did not consider per-shipment submissions to be advantageous and therefore exercised its enforcement discretion and allowed one submission per year per purchaser per country for the first shipment. However, EPA agrees with the commentor who stated that per-shipment notifications would provide useful information. Consequently, EPA is changing its policy to require per-shipment notifications, so that more information about shipments of unregistered pesticides will be available to purchasers and other governments.

EPA recognizes that per-shipment purchaser acknowledgement statements would present a greater burden than the current system. EPA therefore believes that an alternative approach would provide essential information while minimizing the administrative and paperwork burden.

Under the alternative approach, rather than submitting per-shipment purchaser acknowledgement statements, exporters would be permitted to satisfy the purchaser acknowledgement statement requirement as follows. The exporter would submit to EPA a signed purchaser acknowledgement statement for the first shipment each calendar year of an unregistered pesticide to a particular purchaser in a particular country. The exporter would attach to that first purchaser acknowledgement statement sent to EPA, a certification signed by the exporter that export did not take place until a signed acknowledgement statement was received, and provide information which can be used to identify any research and development products (other than those exempt from the purchaser acknowledgement statement requirement, as described at 40 CFR 168.75(b)(2)) referred to by code names in the purchaser acknowledgement statement. In addition, the exporter must include in the signed certification a statement certifying that, for that calendar year, the exporter will submit an annual summary using the procedures detailed in this policy.

Under this alternative approach, the exporter would be required to submit to EPA an annual shipping summary at the end of the year, which summarizes the dates and destinations of all shipments of that pesticide to each particular purchaser exported during the previous calendar year. The annual summary must include the purchaser's name and address, the date of the purchaser's signature in the purchaser acknowledgement statement submitted to EPA during the previous calendar year, the known destinations of the shipment, and the identity of the product and active ingredient(s). The annual summary must be submitted to EPA by March 1st of each year. EPA does not believe the annual summary would be very burdensome because the information should be readily available to exporters in their records of shipments, which they are already required to maintain under 40 CFR 169.2.

EPA will send a copy of the annual shipping summary to the appropriate government officials after it is received.

EPA considered requesting that information on the quantity of pesticides exported be included in the annual summary. EPA believes that while quantity information may be useful in providing more information about exports, it is not necessary to implement section 17(a)(2). In addition, EPA has concluded that this information may be entitled to protection as confidential business information, as discussed in Unit III.C. of this preamble. For these reasons, and for the reasons discussed in Unit III.B.8 of this preamble (Information Requirements for the Purchaser Acknowledgement Statement), EPA has decided not to require it.

In summary, the section 17(a)(2) requirement for a purchaser acknowledgement statement can be met by exporters complying with either of the following two options: (1) Submit a purchaser acknowledgement statement for each shipment of unregistered pesticides; or (2) submit a purchaser acknowledgement statement for the first shipment each year of a particular pesticide to a particular purchaser for each importing country, including the appropriate certification, and submit a report to EPA which lists the dates and

destinations of all shipments exported during the previous calendar year.

The procedures that an exporter of unregistered pesticides must follow in obtaining and transmitting the foreign purchaser acknowledgement statements are set forth in 40 CFR 168.75.

e. *Effective date for 40 CFR 168.75.* Under both the per-shipment option and the annual reporting option for complying with section 17(a)(2), the schedule for obtaining and transmitting purchaser acknowledgement statements is based on the calendar year. However, because this policy has been published several months into a new calendar year, exporters may have already sent EPA purchaser acknowledgement statements under the provisions of EPA's 1980 Pesticide Export Policy. In order to facilitate compliance with this policy, the effective date for the new purchaser acknowledgement statement requirements is June 1, 1993. Thus, all the requirements of 40 CFR 168.75 will be applicable as if June 1 was the start of the 1993 calendar year. Beginning June 1, 1993, exporters must submit purchaser acknowledgement statements on a per-shipment basis, unless the exporter complies with the provisions of the alternative approach of annual reporting procedures as provided in this policy. Under the per-shipment approach, the exporter will have to obtain, prior to each shipment of an unregistered pesticide product to a country, a signed purchaser acknowledgment statement, in accordance with 40 CFR 168.75(c)(2)(i). The exporter must submit the signed purchaser acknowledgement statement to EPA in accordance with the requirements of this policy.

If the exporter chooses the annual reporting procedures, he or she must comply with all the requirements specified in 40 CFR 168.75(c)(2)(ii) effective June 1, 1993. The exporter must obtain, prior to the first shipment occurring after June 1, 1993, of an unregistered pesticide product to a particular purchaser in a country, a signed purchaser acknowledgement statement in accordance with 40 CFR 168.75(c)(2)(ii).

In addition to the purchaser acknowledgement statement for the first shipment, the exporter must submit a certification that he or she is choosing the annual summary compliance option. The exporter must submit the signed purchaser acknowledgement statement and certification in accordance with the requirements of this policy. In March 1994, the exporter choosing the annual reporting option for the June 1, 1993 through the December 31, 1993 period must submit to EPA a summary of shipments of each pesticide to each purchaser sent during that period.

In subsequent years, the period for exporters choosing the annual reporting option will be the calendar year. (Purchaser acknowledgement statements submitted to EPA during the period January 1, 1992 through May 31, 1993, will be governed by the policy published in 1980 (45 FR 50274, July 28, 1980).

6. *EPA's transmittal of purchaser acknowledgement statements.* — a. *1980 policy.* The 1980 policy did not discuss EPA's transmittal of purchaser acknowledgement statements. Under that policy, EPA sent copies of the purchaser acknowledgement statement to the Department of State. Along with the purchaser acknowledgement statement, EPA sent a cover sheet which identified the registration status of the pesticide. (The status is identified as: not registered; denied registration; canceled; or registration status unknown.) The State Department then transmitted the purchaser acknowledgement statement with EPA's cover sheet, to the U.S. diplomatic post in the importing country, which in turn sent it to an appropriate government official in that country.

b. *1990 proposal.* EPA proposed sending purchaser acknowledgement statements directly from EPA to officials in importing countries, and if different, the country or countries of final destination, if known.

c. *Comments.* All commentors supported the idea of direct transmittal of purchaser acknowledgement statements to foreign governments, citing improved timeliness and efficiency.

d. *Response.* EPA intends to implement this approach and has made arrangements to do so. These notices will, therefore, be transmitted directly by EPA to appropriate officials of the country of import and, where reported, to the countries of final destination or intended use. EPA will also send a copy of the annual shipping summary, as discussed in the response to the previous comment, to the appropriate officials after it is received.

EPA has decided that the appropriate governmental official to receive section 17(a) notifications will be the person named as the designated national authority (DNA) for pesticide notifications in the international prior informed consent program (PIC). The DNA has the responsibility for both receiving and disseminating information associated with the PIC procedures. Countries may participate in PIC as either an importing country or an exporting country. Exporting countries are expected to participate in PIC for the purposes of participating in information exchange procedures and export control features. For countries which are not participating in PIC, EPA will ascertain the names of the appropriate persons to receive the section 17(a) notifications.

7. *Format of the purchaser acknowledgement statement.*—a. *1980 policy.* The 1980 policy set forth a recommended content for purchaser acknowledgement statements, but did not recommend or require a specific format.

b. *1990 proposal.* The Agency solicited comments on whether the purchaser acknowledgement statement would be more useful if a specific format were required, or if a particular form were provided, e.g., a form similar to the accepted international form for notification under the PIC program.

c. *Comments.* Nine commentors supported the idea of a standardized format. Four industry commentors expressed strong reservations with using a form or format that closely resembles PIC notification forms for banned or severely restricted pesticides. They pointed out that not all unregistered products are banned or severely restricted and that using a form that closely resembled the PIC notification for banned or severely restricted chemicals would be confusing and misleading. Two commentors suggested following a format designated by FAO/UNEP as the basis for a standardized format for the purchaser acknowledgement statement.

d. *Response.* EPA believes that standardization of purchaser acknowledgement statements would improve the consistency of submitted information and the familiarity of foreign governments with a given format thus expediting review and reducing misunderstandings. Purchaser acknowledgement statements vary greatly in quality and content. Many do not adequately identify the pesticide being shipped or the country of the purchaser. Even though this information is currently required, the lack of a standardized format may make compliance more difficult. EPA believes that a specific format will facilitate compliance, improve information transmittal from exporters, and strengthen the Agency's ability to manage the information contained in purchaser acknowledgement statements.

One of the reasons EPA is considering a format or form for the purchaser acknowledgement statement is to improve the utility of the information provided by the purchaser acknowledgement statements to foreign governments. The Agency agrees with

those commentors who suggested that it would be misleading for the form or format to closely resemble another form which transmits different information. Any forms and/or format which EPA may develop will be reviewed to assure that they cannot be mistaken for PIC notification forms dealing with banned or severely restricted chemicals.

EPA is considering developing and making available purchaser acknowledgement forms in different languages. EPA believes that multilingual purchaser acknowledgement statements would ensure that the documents could be understood by the widest possible audience. If these forms are developed, it is EPA's intent that they will be published in the **Federal Register** for comment. Until the forms are available, any format that is clearly understandable and includes the required information is acceptabl e. In the interim, EPA plans to provide a cover sheet in French, English or Spanish (the official languages of the PIC system) with each purchaser acknowledgement statement EPA transmits to importing governments. EPA believes that cover sheets in the appropriate language will aid countries in understanding and using the information in the purchaser acknowledgement statement.

8. *Information requirements for the purchaser acknowledgement statement.* — a. *1980 policy.* In EPA's 1980 Policy, the Agency stated that the purchaser acknowledgment statement must include the following information:

(1) The exporter's name and address.

(2) The foreign purchaser's name and address.

(3) The name of the product and the active ingredient.

(4) An indication that the purchaser understands that the product is not registered for use in the United States and cannot be sold in the United States.

(5) The destination of the export shipment if different from the purchaser's address.

(6) The foreign purchaser's signature.

(7) The date of the signature.

b. *1990 proposal.* EPA proposed that more information be provided in purchaser acknowledgement statements. Specifically, EPA proposed that the country or countries of final destination be identified in the purchaser acknowledgement statement, so that EPA could begin to send these notices directly to the regulatory officials in these countries. In some instances, this would represent a broadening of the requirement in the 1980 policy, which only required "the destination" of the shipment to be included.

c. *Comments.* There were only a few comments specifically addressing this issue. One commentor supported the proposed expansion to include the country of final destination, while another commentor proposed that the purchaser acknowledgement statements be expanded to include information about the quantity and frequency of the shipments. Commentors from both industry and other governments stated that the country of final destination will often not be known by the exporter at the time of shipment.

d. *Response.* EPA considered other information which could be included in a purchaser acknowledgement statement in order to make the notifications clearer and more useful to other governments. EPA is requiring, as part of this final policy, that exporters provide the Chemical Abstracts Service (CAS) registry number for each active ingredient in a product, the International Union of Pure and Applied Chemists (IUPAC) chemical name for each active ingredient, and other known chemical or common names by which the product is known. The Agency believes this information is necessary for adequate identification of the product and active ingredients. In addition, the identity of the country of final destination should be included in the purchaser acknowledgement statement, to the extent this information is known to, or reasonably ascertainable by, the exporter.

On April 25, 1991, EPA issued a class determination finding that the identity of the country of final destination is not entitled to confidential treatment. A copy of the class determination is reprinted in Unit III.C. of this preamble.

EPA acknowledges that the country of final destination may not be known by the exporter at the time of shipment. As with requirements regarding multilingual language on labels, this requirement is contingent on the exporter having actual knowledge of the country of final destination, or if it can be determined that the information was reasonably ascertainable to the exporter.

In response to the comment received, EPA considered requiring information about the quantity of shipments in purchaser acknowledgement statements. EPA agrees that information about the quantity of unregistered pesticides exported would be useful to other countries, to EPA and to other agencies, and in responding to inquiries from Congress and the public. Information about the quantity of pesticides shipped would give importing countries valuable information for regulating pesticide use in their countries. However, EPA's authority to require quantity information under FIFRA section 17(a)(2) is subject to question and requiring this information could create difficulties in protecting confidential business information from release as required by FIFRA. Therefore, EPA will not require quantity information to be included in the purchaser acknowledgement statements.

9. *Language requirements for purchaser acknowledgement statements.* — a. *1980 policy.* The 1980 policy did not contain any language requirements for the exporter to meet to satisfy the purchaser acknowledgement statement requirement of section 17(a)(2).

b. *1990 proposal.* EPA proposed requiring that purchaser acknowledgement statements be written in English, the language of the purchaser's country, and the languages of the country or countries of final destination. In the case where more than one language is involved because the product is shipped to more than one destination, EPA proposed that the exporter must submit either a multilingual statement to EPA, or multiple statements in all required languages. EPA believed that these changes would assist the purchasers and the importing governments in understanding the contents and significance of the purchaser acknowledgement statements.

c. *Comments.* EPA received many comments on its proposal to make the purchaser acknowledgement statement multilingual. Four governments and the OECD representative supported the proposal, although the latter wondered how EPA would know all of the intended destinations and hence required languages. One environmental group and one industry commentor also supported the proposal.

Most of the commentors from industry objected to the proposal that purchaser acknowledgement statements be multilingual, and some objected to the minimal bilingual proposal as well. Many of the arguments were identical to those raised regarding the proposal that labeling be multilingual. (See 55 FR 4971.) For example, it was pointed out that the country of final destination would not always be known as in the case of an active ingredient exported for reformulation. One commentor stated that the burden of translating the purchaser acknowledgement statements might be disproportionately high on small businesses who may not have multilingual or bilingual staff. Another stated that a foreign purchaser may be reluctant to sign a statement which included language which the purchaser cannot read. This commentor believed

that the requirement of multilingual or bilingual purchaser acknowledgement statement would in practice require foreign purchasers to be adept in all of the languages on the purchaser acknowledgement statement. Most of the industry commentors did not object to the minimal proposed bilingual requirement.

d. *Response.* EPA believes that multilingual purchaser acknowledgement statements would be very useful in communicating necessary information as evidenced by the support for this proposal from foreign governments. However, the numerous comments raised by industry indicate that there are practical problems which need to be addressed. EPA also recognizes that requiring exporters to translate purchaser acknowledgement statements into different languages would place a new burden on industry, particularly small businesses. As noted earlier, EPA is considering developing forms for exporters to use as purchaser acknowledgement statements which are already in different languages. The forms could be developed in English, French, and Spanish, which are the official languages of the PIC program. EPA believes that this approach would be more efficient than requiring each exporter to develop its own multilingual purchaser acknowledgement statements. Due to the number of practical problems to be worked out, EPA does not have such forms at this time, and EPA is considering publication of a proposal on this issue at a later date.

As discussed above in Unit III.B.7. on format of the purchaser acknowledgement statement, until multilingual purchaser acknowledgement statement forms can be developed, EPA plans to include a cover sheet in the appropriate language with each purchaser acknowledgement statement the Agency transmits. There will be no requirement for the purchaser acknowledgement statement to be in multiple languages at this time. However, if the foreign purchaser signs a purchaser acknowledgement statement in their own language, it must be accompanied by an English translation when it is submitted to EPA by the exporter.

C. Confidentiality

1. *Information treated as confidential.*— a. *1980 policy.* EPA's 1980 policy statement permitted exporters to claim all the information required in the purchaser acknowledgement statement as trade secrets or confidential business information (CBI). In the past, and in accordance with its 1980 policy statement, EPA treated information submitted in purchaser acknowledgement statements as confidential within the meaning of its regulations on business confidentiality at 40 CFR part 2, subpart B, when such information had been claimed confidential by the exporter.

b. *January 12, 1990 policy statement.* In the **Federal Register** Notice regarding the confidentiality of certain information submitted under sections 7 and 17(a)(2) of FIFRA, dated January 12, 1990 (55 FR 1261), EPA clarified that section 7(d) of FIFRA excludes the names of the pesticides or active ingredients used in producing pesticides produced, sold, or distributed at an establishment, from protection as confidential business information. In addition, EPA stated that the names of producers of unregistered pesticides are a matter of public record under FIFRA section 4. The notice also explained that since unregistered pesticides generally may be manufactured only for the export market, the fact that a company has submitted a purchaser acknowledgement statement to EPA under section 17(a)(2) for a given pesticide could therefore be determined from public information. Accordingly, the identity of the producer of the unregistered pesticide product, and if applicable, the name of the active ingredient would no longer be accorded confidential treatment by EPA.

c. *Comments and response.* Several commentors in response to the January 12, 1990 notice stated that no information in a purchaser acknowledgement statement should be confidential, asserting that the information was readily accessible to interested parties either in published reports or upon request.

d. *1990 proposal.* The proposed policy on section 17(a) clarified that certain information contained in purchaser acknowledgement statements will not be entitled to confidential treatment. Specifically, the proposed policy clarified that the name and address of the exporter, and the name of the product and the active ingredient will not be considered confidential. In addition, EPA proposed to issue a class determination under 40 CFR 2.207 concerning the confidentiality of country of final destination as reported on purchaser acknowledgement statements. EPA also requested comment on whether a similar determination should be made for information identifying the foreign purchaser.

e. *Comments.* Several commentors stated that disclosure of the country of import and the country of destination, coupled with the non-confidential name of the exported product would be an unfair public disclosure of a company's marketing position. They stated that this would provide an unfair advantage to foreign-based competitors. Some commentors explained in detail the public sources for this information. They explained that the cost of obtaining the information from other sources would not be prohibitively high for well-financed exporters. Exporters stated that while public sources of the information existed, they were not as accurate or as detailed as the information which EPA would make available, should the information be deemed non-confidential.

f. *Response.* EPA's research and inquiries suggest that destination information is generally already a matter of public record. Some countries publish lists identifying monthly pesticide imports, including information on the name or type of pesticide, the exporting company, and the exporting country. Other countries make this information available on request. Information on international markets for particular pesticides is widely available through advertising by U.S. exporters.

In addition, compilations exist which list pesticides and their regulatory status throughout the world, such as volumes published jointly by the Agricultural Requisites Scheme for Asia and the Pacific and the International Cooperation Center for Agricultural Research and Development. Private publishers provide information on pesticide exports at a substantial cost. Battelle publishes "World Pesticide Programs" reports which provide detailed information on pesticide use in foreign countries. "Agrow World Crop Protection News" offers market planning and development information and lists pesticides registered in various countries. The Port Import/Export Reporting Service (PIERS) database of the Journal of Commerce provides information on all shipments leaving the United States. Information available to customers of PIERS includes commodity exported (although the precise identity of the pesticide may not be given), manufacturer or shipper, destination and estimated quantity.

In addition to the availability of destination information in many public sources, EPA believes that treating the country of destination as non-confidential would have public health and environmental benefits. EPA intends to send copies of the purchaser acknowledgement statements to all the countries of destination identified by the exporters on the statement.

Information that particular pesticides are being shipped to their country should provide countries with information useful in monitoring and controlling imported pesticides.

One commentor stated that information on quantities shipped should not be confidential. The 1980 policy did not require information on the quantity of pesticides exported to be submitted as part of the purchaser acknowledgement statement. EPA considered requiring information on quantity in the purchaser acknowledgement statement, and treating this information as non-confidential. Many companies objected to the disclosure of any information on the quantity of pesticide exported. Several companies were concerned that information about quantity sold would substantially harm their companies' competitive positions by revealing information about their market share. These companies claim that any public data about quantity is either estimated or in obscure sources and not currently available in a form that would provide the significant advantage to competitors that EPA's reports would provide.

After research and analysis of this issue, EPA has concluded that while quantity information may be useful in providing more information about exports, it is not necessary to implement section 17(a)(2).

EPA also requested comment on whether a similar determination should be made for information identifying the foreign purchaser. The name and address of the foreign purchaser may be entitled to confidential treatment if it reveals information about the customer list of the pesticide company. However, if the foreign purchaser is merely a distributor for the pesticide company in the foreign country, then this information would not generally be considered privileged.

Several groups commented that there should be no confidential information in a purchaser acknowledgement statement. They claimed that this information may be publicly available or estimated in international trade magazines or other services. EPA believes that companies have a valid interest in protecting information which could divulge their customers or marketing strategies, and thus not all information in a purchaser acknowledgement statement should be treated as non-confidential. One commentor stated that only financial information should be protected as confidential. EPA believes that this is too narrow an interpretation, For example, courts have held that any information that could reveal market share is confidential business information.

Many commentors were concerned about the release of any information on research and development products. Companies indicated that confidentiality would be essential for such shipments to avoid revealing information which could be invaluable to competitors. These commentors stated that information about R&D products including the chemical identity of the research product, the quantity being shipped, the potential use pattern, and the country of final destination should be confidential. Several exporters explained that new products are often developed simultaneously in different countries before the patent status of new research materials has been settled. Most countries, unlike the United States, have a first-to-file patent law, not a first-event law. This means that the identity of an unpatented research compound could be patented without proving that the filer discovered the compound first. Therefore, premature release of R&D information could jeopardize the U.S. producer's patent rights to a new product. Companies also commented that public disclosure would allow competitors to learn about the new areas of chemistry being explored by the exporter. Competitors could explore these new areas and compromise the exporter's competitive advantage in research.

Other commentors stated that R&D information relevant to public health and the environment should not be withheld from the public in the country of import or the public in the United States.

2. *Confidentiality of R&D information.* EPA believes that companies' concerns that the premature release of information about research and development products may lead to a potential loss of patent rights are valid concerns. Therefore, EPA has concluded that information about research and development products is generally entitled to confidential treatment.

3. *Class determination.* Based on the considerations discussed above, and in accordance with its regulations at 40 CFR 2.207, on April 25, 1991, EPA issued a Class Determination (1–91, Identity of Importing Country Under FIFRA section 17(a)(2).), concluding that information on the identity of the importing country, reported to EPA in purchaser acknowledgement statements, is not entitled to confidential treatment under 5 U.S.C. 552(b)(4) of the Freedom of Information Act or FIFRA. The effect of a class determination is to make known the Agency's position regarding the manner in which information within the class will be treated in accordance with the provisions of EPA's confidentiality regulations. Publication of this class determination is not sufficient grounds to release information claimed confidential since both 40 CFR 2.204(e)(1) and 40 CFR 2.205(f)(2) require that before release of information claimed to be confidential, notice must be given by certified mail or by other means by which the date of receipt of the notice can be verified.

Any companies who have previously claimed information about the destination of their export shipments to be confidential, will receive the notice provided for in EPA's regulations before the Agency releases this information. (40 CFR 2.204(d)(2) or 40 CFR 2.205(f).

Persons submitting the information specified in the purchaser acknowledgement statement may assert a claim of business confidentiality by marking the information claimed confidential as "FIFRA Confidential Business Information." Information so claimed will not be disclosed, with the exception of disclosure to the foreign governments, except in accordance with the procedures set forth in 40 CFR part 2, 7 U.S.C. 136(h), and this policy statement. Notwithstanding any claim of confidentiality, the purchaser acknowledgement statement will continue to be forwarded to the appropriate foreign government officials in its entirety, as required by section 17(a)(2).

In summary, the following information will generally not be considered confidential: (a) The fact that a producer makes a registered or unregistered pesticide product; (b) the fact that an acknowledgement statement or other notice of export has been filed by an exporter; (c) the identity of the unregistered exported product; and, if applicable, the identity of the active ingredients of the pesticide; and (d) the identity of the importing country and the country or countries of final destination, if known. Information subject to the following class determination 1–91 will not be considered confidential and claims of confidentiality for this information will be denied.

Class Determination 1-91

Identity of Importing Country Under FIFRA Section 17(A)(2)

I. Background

Section 17(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) sets out the conditions under which pesticides not registered for use in the United States may be exported to other countries. Under that provision and the Environmental

Protection Agency (EPA) statement of policy governing its implementation (45 FR 50274, July 28, 1980), a pesticide which is not registered under section 3 or sold under section 6(a)(1) of FIFRA may be exported only if, prior to export, (1) the foreign purchaser signs a statement acknowledging it understands that the pesticide is unregistered and cannot be sold in the United States and (2) a copy of the acknowledgement statement has been transmitted to EPA for sending to the government of the importing country. Under EPA's policy, these requirements apply only to the first shipment of each unregistered pesticide to a particular purchaser in a given country annually.

EPA's 1980 policy statement permitted exporters to claim as confidential business information required to be reported to EPA on the foreign purchaser's acknowledgement statement. The information required to be reported is as follows:

(a) Name and address of the exporter;

(b) Name and address of the foreign purchaser;

(c) Name of the product and the active ingredient and an indication that the purchaser understands that the product is not registered for use in the United States;

(d) Destination of the export shipment if different than purchaser's address;

(e) Signature of the foreign purchaser; and

(f) Date of the foreign purchaser's signature.

In the past, and in accordance with that policy statement, EPA has treated this information as confidential when so claimed by the exporter. However, EPA issued another policy statement on January 12, 1990 (55 FR 1261) addressing the confidential status of information reported to EPA under section 7 of FIFRA which necessarily affected the confidentiality of certain information reported under section 17(a)(2).

Specifically, because section 7 mandates that certain information is not entitled to confidential treatment, the fact that a company has submitted a notice under section 17(a)(2) for a given pesticide is necessarily public as well. (The active ingredient of that pesticide is also public information).

This class determination addresses the confidentiality of the identity of the importing country of the unregistered pesticide export. It does not address the status of information about the foreign purchaser, information reported about research and development products, or quantity of shipment information which may be recorded on the purchaser acknowledgement statement.

II. Findings

Under EPA's regulations on business confidentiality at 40 CFR 2.207, I have authority to issue class determinations concerning entitlement of business information to confidential treatment. In the case of the information reported to EPA under FIFRA section 17(a)(2) concerning the identity of importing country I have found:

(1) EPA possesses numerous notices filed under FIFRA section 17(a)(2) and will continue to receive such notices in the future.

(2) The information reported concerning importing country is of the same nature and therefore can be treated similarly for the purpose of this determination.

(3) A class determination will serve a useful purpose by simplifying EPA responses to Freedom of Information Act (FOIA) requests for information contained in the notices, reducing the burden of individual determinations and informing requesters and affected businesses of EPA's position in advance.

EPA may withhold information from disclosure under the FOIA if the information falls within one of the exemptions in the Act. One exemption is for "trade secrets" and commercial or financial information obtained from a person and privileged or confidential. 5 U.S.C. 552(b)(4). The matter to be decided in this class determination is whether the identities of importing countries reported under FIFRA section 17(a)(2) are entitled to be withheld from disclosure under this exemption of the FOIA.

The information in question is clearly commercial information obtained from a person. The issue is whether this information is trade secret or otherwise confidential within the meaning of 5 U.S.C. 552(b)(4) and EPA's business confidentiality regulations at 40 CFR part 2, Subpart B.

Before EPA may conclude that information is exempt from disclosure as trade secret or confidential commercial information, the Agency must find that the information is in fact maintained in confidence by the business and is not publicly available. If it is not maintained in confidence or is publicly available, it is not entitled to confidential treatment and EPA must disclose the information.

The weight of evidence shows that destination information on unregistered pesticides is publicly available for many such exports. For example, some countries publish lists identifying monthly imports including information on the name or type of pesticide, the exporting country and the exporting company. Other countries make this information available on request.

Also widely available is information on international markets for particular pesticides. There is widespread advertising by United States exporters on billboards and in stores in foreign countries for pesticides sold in those countries but not registered in the United States. Similar advertising appears in domestic and foreign publications.

There also exist compilations listing pesticides and their regulatory status throughout the world, such as three volumes published jointly by the Agricultural Requisites Scheme for Asia and the Pacific and the International Co-operation Centre for Agricultural Research and Development covering Asia, the Pacific, and Africa.

In addition, considerable information on destination of pesticide exports is available from private publishers at a cost which is high but not prohibitively so for pesticide manufacturers. For example, Battelle publishes "World Pesticide Programme" reports which provide detailed information on pesticide use in foreign countries. "Agrow World Crop Protection News" offers market planning and development information and lists pesticides registered in various countries.

Finally, the Port Import/Export Reporting Service (PIERS) database of the Journal of Commerce provides information on all shipments leaving the United States. Information available to customers of PIERS varies in the level of detail provided, but may include commodity exported, manufacturer or shipper, destination and quantity.

Therefore, it appears that in many instances destination information on unregistered pesticide exports is not maintained in confidence and is in fact available to the public. For those exports, destination information is not entitled to confidential treatment by EPA. Since this determination must cover all notices received under section 17(a)(2), however, it is necessary to continue the confidentiality analysis to apply to those exports for which destination information may in fact be held in confidence.

Information that has been kept in confidence may be entitled to confidential treatment under 5 U.S.C. 552(b)(4) if it meets one of the tests set out in *National Parks Conservation Association v. Morton*, 498 F.2d 765 (D.C. Cir. 1974). Under Morton, commercial or financial information may be withheld from disclosure if revealing the information would be likely (1) to impair the ability of the government to obtain necessary information in the future or (2) to cause substantial harm to the competitive position of the submitter of the information.

The first test is not applicable to export destination information because such information is required to be submitted to EPA under FIFRA 17(a)(2) and EPA's policy statement. Therefore, the information is not voluntarily submitted and EPA's ability to obtain it in the future would not be impaired by disclosure. Accordingly, the applicable Morton test is the second one, whether disclosure of this information would be likely to cause substantial harm to the competitive position of the submitter.

Country of destination information other than information concerning pesticides in the research and development stage is not the type of information that would likely cause substantial competitive harm to a submitter if it were released. If not coupled with information about quantity shipped, the identity of the country of destination does not reveal specific information about the company's customer list or market share. While an argument can be made that releasing information concerning research products could enable competitors to learn new areas of chemistry being explored by the exporter and thwart "first to file" patent laws, no similar argument can be made for pesticides in an established market. Therefore, under the second Morton test, information identifying the country of destination of unregistered pesticide exports is not entitled to confidential treatment.

III. Conclusion

For the foregoing reasons, I find that information reported to EPA under FIFRA section 17(a)(2) on unregistered pesticide exports identifying the importing country is not entitled to confidential treatment under 5 U.S.C. 552(b)(4) or FIFRA.

Date April 25, 1991.

Craig B. Annear

Associate General Counsel

D. FIFRA Section 17(b) Notification Programs

1. *Background.* — a. *EPA's 1975 notice.* In 1975, EPA issued a **Federal Register** notice interpreting the section 17(b) international notification requirement to apply to "information having international significance." (40 FR 20987, May 14, 1975). In that notice, EPA indicated that notices to foreign governments would be sent under two conditions: (1) whenever the Agency registers, under the authority of section 3, a pesticide that contains any new active ingredient or entails a new use, and (2) when cancellation or suspension of a pesticide becomes effective and is determined to be of international significance. In the latter instances, EPA indicated that such determinations would be made by applying general guidance on a case-by-case basis.

In the 1975 notice, EPA also indicated what types of action would be considered to be of international significance:

1. Actions resulting from a review of the pesticide; actions resulting from findings of risk.

2. Actions resulting from decisions to reduce or revoke tolerances under the FFDCA.

3. Actions involving issuance of a new policy applicable to the entire pesticide industry.

4. Actions which may have widespread environmental, economic or political implications.

b. *Current practice.* EPA has generally limited section 17(b) notices to cancellations or suspensions undertaken for health or environmental reasons, and for selected actions which place significant restrictions on a pesticide's use, usually at the conclusion of a Special Review. The section 17(b) notices, as currently designed, discuss in general the health or environmental concerns which prompted the action, and offer to provide additional information upon request. The notices are fairly brief, about three pages in length, and are written in terms easily understood by people who may not be familiar with the U.S. pesticide regulatory program or laws.

Under the current system, EPA's Office of Pesticide Programs prepares a notice and sends it to the Department of State for transmittal to other governments. The State Department transmits a cable to all diplomatic posts, directing embassies to inform the host government of the information in the cable. The embassy then contacts an appropriate government office in the host country and informs the office of the information contained in the cable. Each embassy may handle the notification differently, depending upon individual circumstances. Some notify the Environment Ministry, some inform the Agricultural Ministry, while others may inform the Foreign Ministry which then in turn is expected to inform the pesticide regulatory body. Some embassies may simply provide a copy of the cable, some may set up a meeting to discuss the notice, while others may prepare a formal diplomatic communique to transmit the information.

c. *EPA's goals.* EPA wants to ensure that other governments have information on regulatory actions taken on the basis of public health or environmental concerns involving a pesticide's use. Such information can assist other governments in making informed decisions on the continued use of pesticides in their own countries. EPA believes that providing increased information on pesticide regulatory actions will also help further health and environmental protection goals worldwide. EPA also believes that informing other governments will assist with efforts toward international harmonization, as information about EPA's pesticide regulatory activities may prompt similar actions abroad.

EPA has reviewed the section 17(b) notification program to determine how it fits in with EPA's international goals. EPA wants to inform foreign growers of any U.S. pesticide regulatory action which may affect their ability to export food legally to the United States. If the United States informs other governments of the regulatory actions that the United States has taken with respect to pesticides, those governments may use that information to inform exporting producers or to regulate the application of pesticides on crops destined for export to the United States.

EPA has determined that revisions to its international notification system are warranted. Revisions to the final policy focus on the following areas: The scope of the international section 17(b) transmittals; the frequency of such transmittals and the content of the notifications; and the transmittal process itself. These areas are discussed in greater detail below.

d. *1990 proposal.* EPA requested comment on proposed revisions to its policy on notification of foreign governments of certain types of pesticide regulatory actions. FIFRA section 17(b) requires international notifications whenever a registration, cancellation, or suspension of a pesticide's registration becomes effective, or ceases to be effective. Since a major objective of EPA's review of its section 17(b) policy was to improve the utility of the notification process to recipients, EPA sent copies of the proposal out for comment to foreign countries and international organizations.

EPA proposed to broaden the scope of section 17(b) notifications to include all actions taken on the basis of health or environmental concerns, to increase the frequency and to amend the transmittal process for the notifications.

1. *Scope of section 17(b) notification program.* EPA proposed to expand the scope of actions subject to international notification to include all regulatory actions taken on the basis of health and environmental criteria so that countries receive important information about pesticide risks. EPA also proposed that countries should be notified of all major actions which affect pesticide use, including actions which eliminate all registrations for an active ingredient or substantially change a pesticide tolerance.

a. *Types of regulatory decisions.* Every year, EPA takes thousands of different types of regulatory actions affecting pesticide products. These actions encompass routine, noncontroversial decisions, as well as regulatory actions that involve highly contentious issues, and those which address serious concerns about public health and environmental risks. EPA considered a number of factors in determining which regulatory actions should be subject to the notification requirement, and in determining how the information should be transmitted. Among the factors to be considered are: statutory requirements; EPA's policy goals for international pesticide efforts; consistency with international activities; the value of the information to the recipient; and competing demands on EPA's and other agencies' resources.

b. *Legislative mandate.* A literal reading of section 17(b) (see Unit II.B.2 of this preamble) could require thousands of notifications annually: every time EPA amends a registration; cancels a registration for failure to pay maintenance fees; or cancels a registration at the request of a registrant. EPA believes that this requirement should be interpreted consistent with the intent of Congress to provide meaningful information to other countries (S. Rept. No. 92–1540, 92nd Cong. 2d Sess. at 33 (1972)).

In the 1975 Notice, EPA noted that the legislative history of section 17(b)

indicates that notices should serve a useful purpose. EPA went on to conclude that it would not serve a useful purpose to transmit notices for all of the actions which could conceivably fall within the scope of this requirement, and in fact, that notification of routine actions would likely lessen the impact of information having international significance. This interpretation has guided EPA in its decisions to transmit notices.

In the February 1990 **Federal Register** notice, EPA proposed that section 17(b) notices should encompass all actions taken on the basis of health or environmental considerations. EPA also proposed that section 17(b) should encompass all major actions which affect pesticide use. This would include actions affecting foreign growers who wish to export food to the United States.

c. *Comments.* All commentors on this issue supported expanding the scope of actions subject to section 17(b) notifications. Two commentors supported the scope of actions for section 17(b) actions as proposed, including an annual summary of the actions that meet EPA's criteria. Two commentors suggested sending notices for all new registrations. Another commentor suggested sending notices for all partial cancellations and suspensions. Three commentors supported sending notices on those pesticides withdrawn from the market for other than health or environmental reasons.

d. *Response.* EPA proposed that section 17(b) notices should be sent for proposed and final suspensions and cancellations taken as a result of the pesticide's potential to cause unreasonable adverse effects (FIFRA sections 6(b) and 6(c).) EPA believes that information about final actions taken on the basis of health and environmental criteria would be the most critical for timely international notifications and will continue to send such notices under section 17(b).

However, EPA will continue to advise other nations about major proposed actions so that they will be aware of emerging health and safety concerns, and will have an opportunity to participate in the regulatory process. These notices allow other countries an opportunity to participate in our decisions, and they set an example we are encouraging other countries to follow. Moreover, sending these notices would be consistent with the U.S. negotiating positions in the General Agreement on Tariffs and Trade (GATT) and the North American Free Trade Agreement (NAFTA), and such notifications would be required once these agreements are adopted.

Partial cancellations or suspensions which occur for administrative reasons, e.g., failure of the registrant to pay the fee required would not impart particularly significant information to the recipients of the notices. However, because this information may still be of interest to other countries, a summary of all pesticide regulatory actions will be sent annually, including the actions for which no section 17(b) notices would be prepared on a routine basis, as described in this section.

EPA has decided to expand the scope of actions which will trigger section 17(b) notifications, to include a general category of other actions which EPA determines to be of international significance. This addition is designed to provide the Agency with the flexibility to report on any regulatory actions which may not clearly fit into other categories on the list of actions triggering a section 17(b) notice, as listed below.

(1) Final suspensions/cancellations as a result of the potential to cause unreasonable adverse effects (sections 6(b) and 6(c)).

(2) Denial of a tolerance following a formal finding that the tolerance does not meet the statutory safety standard.

(3) Denial of an application to register a pesticide product following a formal finding that the risks outweigh the benefits.

(4) Voluntary cancellations of a registration where there is evidence of health or environmental concerns (section 6(f)).

(5) Voluntary withdrawals of registration applications, registrations, or tolerance petitions, where there is evidence of health or environmental problems prior to the withdrawal.

(6) Reregistration actions-issuance of a reregistration eligibility decision document (section 4(g)(2)).

(7) Final actions to establish a new tolerance or exemption from a tolerance, to revoke a tolerance or exemption, or to amend a tolerance.

(8) All registrations of a new active ingredient and (if different) the first food use registration of an active ingredient.

(9) All other actions which eliminate all or virtually all significant registrations for an active ingredient including:

(i) Final cancellations for failure of a registrant to meet conditions of registration.

(ii) Voluntary cancellations.

(iii) Cancellations for failure to pay the fee required to reregister or maintain registration.

(iv) Cancellations resulting from other activity under FIFRA section 4.

(12) Any other pesticide regulatory actions which EPA deems to be of international significance.

No section 17(b) notices would be prepared on a routine basis for the following actions. However, these actions will still be included in the annual summary of pesticide regulatory actions.

(1) Registrations of new uses of a pesticide.

(2) Registration of new products with uses similar to existing registered uses (known as "me-too" registrations).

(3) Suspensions for failure to submit data under FIFRA section 3(c)(2)(B) that do not result in the elimination of all or virtually all uses of an active ingredient.

(4) Cancellation/suspensions that do not result in elimination of the registration of all or virtually all uses of the active ingredient or are not taken for health and environmental reasons (eg., voluntary cancellation of a product by a company because of insufficient funds or unwillingness to meet data requirements for reregistration.)

(5) Voluntary withdrawals of petitions for tolerances within 75 days after receipt of a notification from EPA of deficiencies in the data required to support the petition. (See EPA's notice of policy concerning abandoned and incomplete pesticide petitions for tolerances or food and feed additive petitions, 56 FR 43759 (September 4, 1991).

2. *Timing and frequency of section 17(b) notifications.*-(a) *1990 Proposal.* EPA proposed that the timing of section 17(b) notices should depend upon the potential effect of the action taken. Notifications of regulatory actions based on health and/or environmental concerns should be transmitted as soon as possible after such actions are taken. The Agency also proposed to send an annual summary of pesticide regulatory actions taken during the year.

(b) *Comments.* Ten commentors supported the option EPA proposed-to transmit notices of urgent health and environment concerns immediately and to prepare an annual report summarizing these notices and listing less urgent actions taken during the year. One commentor supported maintaining the current system of sending section 17(b) notices as soon as possible after the action occurs.

(c) *Response.* EPA will prioritize the section 17(b) notices to ensure that those dealing with significant health and/or environmental concerns are transmitted immediately. The Agency will also prepare an annual summary of all pesticide regulatory actions and

transmit it to countries. The annual summary will list pesticide regulatory actions published in the **Federal Register** during the year.

3. *Transmittal of section 17(b) notices.* — (a) *Current practice.* EPA transmits both section 17(a) and section 17(b) notices through the State Department. The section 17(a) notices are sent by the State Department to the appropriate embassy for the country of import. The State Department also sends copies of section 17(b) notices to all embassies for delivery to contacts within each country. FIFRA section 17(b) provides that EPA shall transmit section 17(b) notifications through the State Department.

The current practice of transmittal has proved to be a timeconsuming and somewhat inefficient process. The State Department orders all the cables it transmits in terms of priority. Information about domestic regulatory actions is usually of a lower priority than diplomatic activities. Further, embassies may lack sufficient staff to forward the notices quickly to the appropriate government officials in the receiving countries. The current process often delays receipt by foreign governments of information about U.S. pesticide actions.

(b) *1990 proposal.* The Agency proposed to transmit section 17(b) notices directly to the appropriate officials in other governments, with copies of the notices provided to the State Department to keep them informed about the communication.

(c) *Comments.* All commentors except one supported the direct transmittal of section 17(b) notices. The commentor who opposed EPA's direct transmittal of the notices stated that since the statute requires EPA to go through the State Department in transmitting notices, they could not condone EPA's proposal to act on discretionary authority and not follow the explicit statutory provision.

(d) *Response.* EPA will continue to send section 17(b) notices to the State Department for transmittal to embassies. In addition, EPA will send advance notices of actions covered by section 17(b) requirements directly to the appropriate officials in other governments. EPA will also prepare an annual summary of actions covered by section 17(b). EPA will send the annual summary of actions directly to appropriate officials in other governments and simultaneously to the State Department.

4. *Content and format of the section 17(b) notices.* The section 17(b) notices currently contain a summary of the action taken, an explanation of the health or environmental reasons prompting the action, and the legislative and regulatory background for the action. The notices state that additional information is available upon request, usually in the form of a technical support document or fact sheet. There is no current standardized format for section 17(b) notices.

a. *1990 proposal.* In the proposed policy statement, EPA proposed expanding the content of the section 17(b) notifications and solicited comment on the kinds of information which should be included in the notices and the appropriate format, particularly for the annual summary that will include listings of all actions taken during a calendar year. EPA stated that it intends to comply with recommendations for formats made by international organizations when revising the EPA notices, and requested comments on this point.

b. *Comment.* The Agency received few comments on this issue. Two commentors stated that the information in section 17(b) notices should be easily understood, not just a copy of the **Federal Register** notice describing the action. In addition, the same commentors agreed with EPA's proposal to follow an internationally agreed upon format, when possible. Three commentors suggested including the name, address, telephone and Facsimile (FAX) number of EPA contacts with the notice.

c. *Response.* EPA agrees with all comments on this issue. EPA believes it would be useful to expand the information contained in section 17(b) notices. For example, in some cases more information about alternative pesticides, handling, storage and disposal could be provided. EPA has decided to expand the information it includes in section 17(b) notifications to the extent it is available, and consistent with the need for prompt notification. EPA is also considering providing Spanish and French translations of section 17(b) notices upon request. (English, Spanish, and French are the official languages FAO/UNEP will use in implementing PIC notification procedures.)

EPA plans to incorporate, to the extent possible, some of the information used in the FAO/UNEP notification of control action form for section 17(b) notifications. EPA will clearly indicate that the notice is pursuant to section 17(b) of FIFRA, so as not to confuse the recipient. The FAO/UNEP form includes the following information: the Chemical Abstract System registry number of each active ingredient, trade names and the chemical nomenclature used by the International Union of Pure and Applied Chemists (IUPAC), a description of the regulatory action to ban or severely restrict the active ingredient and a reference to the national document ordering such action, a description of reasons for the action relevant to protection of health and the environment, and a discussion of known alternatives.

EPA will also notify the FAO/UNEP Secretariat, using notification of control action forms, of all final actions which meet the internationally-agreed upon definitions of "banned or severely restricted for health or environmental reasons." This will place all relevant information into an international data base and information exchange procedure.

E. Section 17(d) Activities

1. *Prior Informed Consent System.* In 1989, FAO and UNEP jointly adopted procedures to augment their existing guidelines for notification and information exchange among countries. The procedures are known as Prior Informed Consent (PIC) for trade in pesticides and industrial chemicals which have been banned or severely restricted (57 FR 58390, December 9, 1992). FAO will manage the program for pesticides, while UNEP will manage the program for industrial chemicals. The information exchange system, of which PIC is a part, also includes procedures for information exchange on regulatory actions which do not fall within the definitions of banned or severely restricted.

The primary objective of the PIC procedure is to establish a system in which participating importing countries will get information concerning chemicals whose use is banned or severely restricted in other countries; decide whether to allow, restrict, or stop the future imports of such chemicals; and notify other countries on a formal basis of their decision concerning importation and use. The fundamental principle of the PIC system is that international shipment of a chemical that is banned or severely restricted in order to protect human health or the environment should not proceed without the agreement or contrary to the decision of the designated national authority in the importing country.

The PIC procedures require that countries banning or severely restricting a pesticide or industrial chemical for health or environmental reasons (including voluntary withdrawals and refusal to grant first registration when these actions are taken for health or environmental reasons) notify the FAO/UNEP joint program.

All participating countries will receive information on the health or environmental reasons why bans or severe restrictions have been placed on the use of chemicals or pesticides. Upon request, they may also receive further information and/or technical assistance that may be helpful as they make a decision regarding continued use in their countries. Participating importing countries then notify FAO/UNEP of their decisions on whether the import of a PIC chemical will be allowed in the future, and if so, under what conditions. The PIC system provides a mechanism for formal dissemination of the decisions of importing countries to exporting countries. Exporting countries are requested to share the responsibility for controlling the export of such chemicals, and to communicate the decisions of participating importing countries to their export industries.

The United States is a strong supporter of the PIC procedures. In the February 12, 1990 proposal, EPA requested comment on how best to facilitate industry compliance with PIC under FIFRA, which as noted above, provides limited authority for EPA to prohibit pesticide exports if section 17 labeling and notification requirements are met. EPA received two comments on this issue. One country, and one private group commented that self-policing or self-auditing techniques would not be adequate to ensure shipments do not occur contrary to the decisions of importing countries. One of the commentors stated that statutory obligations, supported by official inspections and audits are necessary to ensure compliance with PIC.

EPA agrees that FIFRA should be amended to provide EPA with statutory authority to implement PIC fully with respect to United States pesticide exports. Acknowledging that under current FIFRA authority, the Agency has limited authority to prohibit pesticide exports, EPA intends to implement the PIC system as fully as possible, consistent with U.S. law.

On December 9, 1992, EPA published a **Federal Register** notice announcing the Agency's participation in the PIC procedures, and discussing EPA's submission of two lists of chemicals which are either banned or severely restricted in the United States. The notice also discusses EPA's plan to hold a public forum to discuss U.S. involvement—that of government, industry, and the public—in the PIC process, as well as the Agency's international notification programs under FIFRA and TSCA. (57 FR 58390.)

2. *Consistency between section 17(b) notifications and PIC implementation.* Generally, EPA's section 17(b) notification program covers a much broader range of regulatory actions than the notices which countries will be required to submit under the PIC procedures. The PIC system focuses on two categories of regulatory actions: pesticides and industrial chemicals which are "banned" or "severely restricted."

The *FAO International Code of Conduct on the Distribution and Use of Pesticides* defines "banned" as "a pesticide for which all registered uses have been prohibited by final governmental regulatory action, or for which all requests for registration or equivalent action for all uses have, for health or environmental reasons, not been granted."

The *Code of Conduct* defines "severely restricted" as "a limited ban-a pesticide for which virtually all registered uses have been prohibited by final governmental regulatory action but certain specified registered uses remain authorized."

Countries are not to report on proposed actions. Only pesticides and industrial chemicals which have been banned or severely restricted by a final government action, or due to voluntary cancellation by industry, may be listed. (However, voluntary cancellations should only be reported to FAO/UNEP where there is clear evidence that the pesticide is withdrawn for health and/or environmental reasons.)

EPA plans to review draft section 17(b) notices as they arise to see whether the actions described in the notices would also trigger notification under the PIC system. EPA has considered whether notification through the PIC procedures can or should substitute for direct notification to foreign governments of section 17(b) notices. EPA believes that allowing this substitution in those cases where the regulatory action described in the section 17(b) notice would also trigger a PIC notice will reduce the burden and cost to EPA and avoid possible confusion to those receiving and managing duplicative information. Therefore, the Agency intends to use PIC procedures to transmit notices to countries participating in PIC who have established a designated national authority on the FAO/UNEP list, rather than send duplicative section 17(b) notices.

For countries which do not have a designated national authority, EPA will obtain information on the appropriate person to contact and transmit section 17(b) notices as described in this final policy statement.

3. *Supporting environmental protection in other countries.* EPA's efforts to assist in the protection of public health and the environment in other nations follow two tracks. First, EPA provides information through the notification programs mandated by FIFRA section 17. Secondly, EPA supports the development of decision-making capabilities and regulatory infrastructures in pesticide importing countries.

There are many ongoing projects designed to assist the development of effective pesticide regulatory systems and to promote safer pesticide use in developing countries.

One example is EPA's work with the U.S. Agency for International Development (AID) to develop a comprehensive pilot program to improve pest and pesticide management in Central America. The overall goals of the project are to enhance public health, environmental protection and food safety in both the United States and Central American countries. The project will be coordinated with ongoing activities under the auspices of FAO to establish an international system of information exchange and "prior informed consent" with respect to international trade in pesticides and other efforts to strengthen the regulatory capabilities of developing countries.

Collaboration between EPA and AID will focus on the following three areas:

(a) Strengthening Regulatory Institutions by providing training, technical assistance, and information to the Central American national and regional entities involved in the regulation of pesticide importation, distribution, use and disposal.

(b) Support for AID Food Export Programs by providing information that will assist Central American countries in meeting U.S. pesticide tolerance requirements.

(c) Pesticide management and safety training, including the development of training and technical assistance programs designed to promote and encourage the adoption of appropriate pest management practices.

In connection with the development of the pilot project, EPA organized and conducted a workshop with AID in San Jose, Costa Rica in November 1990. The workshop focused on the U.S. pesticide regulatory system, with the aim of familiarizing Central American countries with regulatory requirements and procedures, particularly as they apply to foods intended for export to the United States. The Agency for International Development, the U.S. Food and Drug Administration, and the

U.S. Department of Agriculture all participated.

Another component of the Central American project is the development of joint FDA-EPA laboratory assessment and enhancement activities, which will include a survey of current laboratory capabilities in the region, technical assistance and training in analytical methods and quality control, access to pesticide reference standards, and other forms of technical cooperation.

During 1991, EPA officials participated in interagency meetings with Mexican governmental officials in Mexico City and in Washington, DC to exchange information on regulatory procedures as well as specific chemicals of concern, to discuss plans for upgrading pesticide regulation and enforcement, and to explore proposals for reducing violative residues on food imported into the United States.

In 1990, EPA, at the request of AID and USDA, participated in a AID-organized disposal workshop for West African countries in Niamey, Niger. The focus of the workshop was mitigation of environmental problems resulting from storage and disposal of pesticides. In 1990, EPA provided technical assistance in storage and disposal to Guinea Bissau.

Other examples of EPA's recent international pesticide activities include: co-sponsoring regional workshops with the United Nations' FAO, on strengthening pesticide regulation in Asia and the Pacific Islands, Latin America and the Caribbean; participation in an international meeting in Beijing, China, on international harmonization of pesticide tolerance levels; and numerous other international technical meetings. EPA continues to host numerous international visitors to provide training in a variety of areas, including regulatory development, data evaluation, decision methods and procedures for pesticide regulation; and to provide expert staff participation in international workshops and technical assistance activities.

EPA has also developed projects jointly with the U.S. Peace Corps. Through a Memorandum of Understanding (MOU) signed with the U.S. Peace Corps in September of 1989, EPA has provided technical assistance through the provision of EPA expert trainers and training materials and participation in training needs assessments. EPA participated in an assessment of pesticide use and regulation in Ecuador and Paraguay, particularly with respect to the Peace Corps volunteer sites and positions. In 1990, EPA conducted training on pesticide safety for 28 Peace Corps volunteers in Ecuador, and provided bilingual training materials on pesticide application and safety, for this and future training.

4. *Harmonizing U.S. and international standards.* EPA recognizes that protecting the global environment and the public health of all peoples must be a truly cooperative international effort. Through participation in the activities of international organizations, EPA promotes the development of consistent methods and standards to meet these common objectives. Encouraging the development of pesticide standards which promote effective environmental and public health protection worldwide also serve to minimize unnecessary disruption of international trade. While EPA recognizes that environmental regulation which is not based on sound science and risk management policy should not be used to enact unfair trade barriers, EPA will not relax science-based standards which protect public health or the environment in order to harmonize them with standards established elsewhere.

EPA participates in activities aimed at promoting harmonization of science-based pesticide regulatory requirements and resolving problems that may result from differing standards that may raise allegations of unjustified restrictions on international trade. Examples of these activities are: the provision of information on proposed regulatory actions (e.g., cancellations, suspensions, tolerances or tolerance revocations); EPA's participation in the General Agreement on Trade and Tariffs (GATT) Uruguay Round negotiations on sanitary and phytosanitary measures; discussions in connection with the negotiation of a North American Free Trade Agreement; the Rome Conference on Food Standards, Chemicals in Food and Trade, (an international meeting jointly sponsored by FAO and the World Health Organization (WHO) in March 1991); and in numerous FAO expert meetings and Government Consultations. In addition, EPA actively supports the Joint Meeting on Pesticide Residues (JMPR) and the Codex Committee on Pesticide Residues (CCPR), providing resources and temporary expert advisors to assist in scientific deliberations. EPA also participates in periodic meetings with its counterparts in Canada, the United Kingdom, and the European Community to discuss pesticide regulation and food safety issues.

IV. Technical Amendment

A. Revising Section 169.2(h)(3) to Conform With the Requirements of this Policy

Section 169.2(h) contains recordkeeping requirements for exporters of pesticides, devices, and active ingredients used in producing pesticides intended solely for export to any foreign country. The second sentence of paragraph 3 of section 169.2(h) discusses the requirement to obtain a foreign purchaser acknowledgement statement pursuant. EPA is deleting this sentence in order to make section 169.2(h) consistent with this policy.

V. Public Record

EPA has established a public record for this final policy statement under docket number OPP–170003. Included in the record are two proposed policies (dockets number OPP–170000 and 170001), as well as copies of public comments received on the proposed policy statements. The record is available for inspection in Room 1128, Crystal Mall 2, 1921 Jefferson Davis Highway, Arlington, Virginia.

VI. Other Regulatory Requirements

A. Executive Order 12991

Under Executive Order 12291, EPA must judge whether an action is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. EPA has determined that this policy does not constitute a major action because it does not meet any of the criteria set forth and defined in section 1(b) of the Order. Costs were estimated based on existing program experience, including the number of annual submissions presently made to EPA that would be affected by changes.

This policy was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any comments from OMB to EPA and any EPA response to those comments are available for public inspection in the public file at the Public Docket location listed under the Public Record section cited above.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, (5 U.S.C. 605(b)), EPA has determined that this policy will not have a significant economic impact on a substantial number of small businesses. The recordkeeping required would easily be satisfied by the normal invoices that are a necessary part of all overseas transactions. The purchaser acknowledgement statements required

to be signed could be included with sales contracts signed by the foreign purchaser. The cost of reporting to the Agency as shown in the information collection burden statement is minimal. A requirement that the purchaser acknowledgement statement be multilingual was not included in the final policy for a number of reasons, including comments that the cost to small businesses could be prohibitive.

C. Paperwork Reduction Act

This policy amends provisions of the foreign purchaser acknowledgement statement requirement of the export policy for unregistered pesticides, which is currently cleared by the Office of Management and Budget (OMB) under control number 2070–0027. The information collection requirements imposed by this policy statement have been submitted to OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. A copy of the information collection request (ICR) document may be obtained from the Information Policy Branch of the Office of Policy, Planning and Evaluation (OPPE) of EPA at the address given below.

Annual respondent burden for this collection of information is estimated to average .92 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An estimated 976 responses annually are anticipated, for a total annual burden of 895 hours. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM–223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

List of Subjects 40 CFR Parts 168 and 169

Advertising, Exports, Labeling, Pesticides and pests, Policy statements, Reporting and recordkeeping requirements.

Dated: January 19, 1993.

William K. Reilly,

Administrator.

Therefore, 40 CFR chapter I, parts 168 and 169 are amended as follows:

PART 168—[AMENDED]

In part 168;

a. The authority citation for part 168 continues to read as follows:

Authority: 7 U.S.C. 136–136y.

Subpart C [Reserved]

b. Subpart C is added and reserved.

3. Subpart D is added to read as follows.

Subpart D — Export Policy and Procedures for Exporting Unregistered Pesticides

Sec.

§ 168.65 Pesticide export label and labeling requirements.

(a) *General.* This section describes how EPA interprets and will enforce the requirements of FIFRA section 17(a)(1). Every exported pesticide, device, and active ingredient used in producing a pesticide (see § 152.3 of this chapter for the definition of "active ingredient" and "pesticide") must bear a label or labeling which meets the requirements of FIFRA section 17(a)(1). This requirement applies to all such pesticides, devices, or active ingredients, regardless of whether the export is for commercial or research use. In the case of unregistered pesticides, including research substances which are being exported for testing, the labeling requirements of this section continue to apply independently of whether the exporter must submit a purchaser acknowledgement statement under FIFRA section 17(a)(2) as described at § 168.75 of this chapter. In addition, information which will satisfy FIFRA section 2(q)(1)(E), (G), and (H) and section 2(q)(2)(A) and (D) must appear in English and in the appropriate foreign languages, on the label or labeling as described in paragraph (b)(4) of this section. The required label and labeling statements may be met through either immediate container labels, accompanying supplemental labeling as described in paragraph (c) of this section, or a combination of the two.

(b) *Specific requirements.* The labels and labeling of any exported pesticides, devices, and active ingredients used in producing pesticides must meet the requirements regarding label and labeling content, correct representation, and understandability as stated in this paragraph.

(1) *Label contents.* The term "label" means the written, printed, or graphic matter on or attached to the immediate container of the pesticide, device, or active ingredient used in producing a pesticide. In the case that the immediate container is enclosed in an outer container or wrapper through which the label cannot be read, the label must also be on such outer container or wrapper. Except as provided in paragraph (c) of this section, the immediate container of the pesticide, device, or active ingredient used in producing a pesticide must bear a conspicuous and readable label which includes:

(i) *EPA pesticide producing establishment number.* The producing establishment registration number must be present but may appear anywhere on the label or immediate container in accordance with the establishment registration labeling requirements set forth in § 156.10(f) of this chapter.

(ii) *Warning or caution statements.* Warning or caution statements must appear on the label and must be adequate for the protection of persons handling the pesticide, device, or active ingredients including warnings regarding general toxicological hazards and environmental, physical, or chemical hazards. Warning and caution statements must appear in English and in the appropriate foreign languages, as described in paragraph (b)(4) of this section. Where the U.S. warning or caution statement, as translated, is obviously inappropriate to protect residents of the importing country, (for example, where a statement calls for a gas mask meeting the specification of the U.S. Bureau of Mines) an equivalent caution must be substituted.

(iii) *The statement "Not Registered for Use in the United States of America."* The labels of all pesticides, devices, and active ingredients which are not registered for use in the United States under FIFRA section 3 must prominently display the following statement: "Not Registered for Use in the United States of America." The statement must appear in English and in appropriate foreign languages, as described in paragraph (b)(4) of this section. It is permissible to append explanatory text which qualifies the statement by pointing out the reasons for the unregistered status. Examples of possible additional statements are "Not Registered for Use on...", "No Longer Registered for Use...", or "Not Registered...because..." Such additions must not be misleading or misrepresent the registration status of the pesticide. The statement "Not Registered For Use in the United States of America" must also be present.

(A) A pesticide is considered registered for the purposes of the section 17(a)(1) requirement only when:

(*1*) A label and labeling approved under a current FIFRA section 3 registration for the product is either attached to the immediate product container or accompanies the product at all times as supplemental labeling as provided in paragraph (c) of this section.

(*2*) The formula of the exported product is the same as the formula of the U.S. registered product (within certified limits). In addition, a change in the color or fragrance of the export product will not affect the product's registration status, as long as the following conditions are met:

(*i*) The change in color must result only from the addition of a dye included on the list of the chemicals exempted from the requirement of a tolerance at § 180.1001, and the dye must not be a List 1 inert. (List 1 inerts are those inerts which the Agency has identified as presenting toxicological concerns. The classification of inerts is explained in EPA's Policy Statement on Inert Ingredients in Pesticide Products, which can be obtained from the Office of Pesticide Programs public docket, Room 1128, Crystal Mall 2, 1921 Jefferson Davis Highway, Arlington, Virginia 22202.

(*ii*) The change in fragrance must result only from the addition of a chemical included on the list of chemicals exempted from the requirement of a tolerance (§ 180.1001) and the chemical must not be a List 1 inert.

(*iii*) The change in fragrance must not result in a pesticide product containing a food or food-like fragrance. (See "Food Fragrances in Pesticide Formulations," EPA's Office of Pesticide Programs Policy and Criteria Notice number 2155.1, November 20, 1975 which can be obtained from the Office of Pesticide Programs public docket, Room 1128, Crystal Mall 2, 1921 Jefferson Davis Highway, Arlington, Virginia 22202.).

(*iv*) Any differences in color or fragrance of the export product in accordance with this section must be reflected in records which show the complete formula of the export product in accordance with the requirements of § 169.2 and this policy.

(*3*) No statements which appear on any of the product labels or labeling add new uses or claims or in any way contradict the approved FIFRA section 3 labeling. However, certain minor changes may be made to a product's labeling or packaging without affecting the registration status of the product, as specified in § 152.46(b) of this chapter.

(iv) *The ingredient statement.* The ingredient statement must appear on the label in English and in appropriate foreign languages (as described in paragraph (b)(4) of this section). If the English language description of the ingredients is easily identifiable and likely to be understood by the ordinary individual, the foreign language ingredient statement need not be included on the label. In the case of pesticide products, devices and active ingredients shipped solely for research and development purposes, it is permissible to use coded identification of ingredients on the label in order to protect confidentiality, in accordance with the requirements of §§ 168.75(c) and 168.85(a).

(v) *Identity of parties.* The name and address of the producer, registrant (if any), or the person for whom the pesticide was produced, must appear on the label.

(vi) *Weight or measure.* The net weight must appear on the label in either English or metric units.

(vii) *Additional warning for highly toxic pesticides.* If the pesticide, device or active ingredient is highly toxic to humans, the skull and crossbones, the word "Poison", and a statement of practical treatment must appear on the label. The word "Poison" and the statement of practical treatment shall be in English and in the appropriate foreign languages, as described in paragraph (b)(4) of this section. The skull and crossbones may be in red or black. For criteria on what pesticides are highly toxic, see § 156.10(h) of this chapter.

(2) *Use classification statement.* In addition to the label contents described in paragraph (b)(1) of this section, the labeling must include a use classification statement, if a use classification has been assigned under a FIFRA section 3 registration. The use classification shall accurately describe the use classification applicable to the U.S. registered use of the pesticide, device or active ingredient (e.g., "Restricted Use Pesticide"). Summary statements describing the use classification, e.g., "For retail sale to and use only by Certified Applicators...", or explaining what such terms mean are not required, but may be included if such statements do not result in false representation of the U.S. regulatory status of the pesticide. The use classification information may appear on the product label or on the labeling accompanying the pesticide product during shipment.

(3) *Misrepresentation.* The labeling shall not make false or misleading representations or represent the product as an imitation of other products.

(4) *Understandability.* The required statements must be expressed in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use. To satisfy this section, certain information described in paragraph (b)(4)(i) of this section, which appears on the labeling of all exported pesticide products, devices and active ingredients must appear in English, in an acceptable language of the country of import as defined in paragraph (b)(4)(ii) of this section, and in an acceptable language of the country of final destination, if known or reasonably ascertainable by the exporter. When there are several official languages or dialects in a country, the language which is predominately spoken or written, or a language in which official government business is conducted, will be acceptable.

(i) *Information required to be multilingual.* The following labeling information must be multilingual:

(A) The warning and caution statements.

(B) Where required, the statement "Not Registered for Use in the United States of America."

(C) The ingredient statement.

(D) Where required in accordance with paragraph (b)(1)(vii) of this section, the word "Poison" and the statement of practical treatment in case of poisoning.

(ii) *Acceptable languages.* In all cases, English must be one of the languages used on the label or labeling. In addition, either the language which is used to conduct official government business, or the predominantly spoken or written language of the country of import must appear on the labeling. In each case where a country of final destination is known, the language which is used to conduct official government business or which is predominantly spoken in that country, if different from the language of the country of import, shall also appear on the labeling. In any case where English is predominantly spoken or written or is the language used to conduct official government business in a country, no other language need be included to meet the multiple language requirement of this paragraph.

(c) *Supplemental labeling.* A pesticide, device or active ingredient intended for export will not be considered in violation of the labeling requirements of FIFRA when the label and/or labeling requirements stated in paragraph (b) of this section are met by supplemental labeling. Supplemental labeling must be attached to the

immediate product container or the shipping container of the pesticide, device or active ingredient at all times when it is shipped or held for shipment to meet export label requirements. Supplemental labeling must meet all of the label requirements in paragraph (b) of this section which are not met by the immediate product labels. Supplemental labeling will satisfy the labeling requirements of FIFRA only if the following conditions are met:

(1) *Applicability.* The use of supplemental labeling applies to any situation where the labeling requirements specified in this section are not met fully on the product label which is attached to the immediate product container. Any required label or labeling statement not met on the immediate container may be met through supplemental labeling.

(2) *Labeling contents and relation to shipment.* If supplemental labeling is used to meet any of the labeling requirements of FIFRA section 17(a)(1), it must meet all of the requirements in paragraph (b) of this section which are not met by the label on the immediate product container. Thus, the supplemental labeling, together with the immediate product container label will meet all of the requirements of paragraph (b) of this section. Where used, supplemental labeling must be attached to or accompany the product shipping container of the pesticide, device, or active ingredient used in producing a pesticide at all times when shipped or held for shipment in the United States.

§ 168.75 Procedures for exporting unregistered pesticides-purchaser acknowledgement statements.

This section describes how EPA interprets and will enforce requirements of FIFRA section 17(a)(2). Section 17(a)(2) provides that any person exporting a pesticide other than a pesticide registered for use under FIFRA section 3 or sold under FIFRA section 6(a)(1), shall obtain a statement signed by the foreign purchaser prior to export, acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States. Section 17(a)(2) requires that a copy of the statement be transmitted to an appropriate official of the government of the importing country.

(a) *Products subject to the requirement.* EPA will not consider an exporter of an unregistered pesticide to be in violation of FIFRA section 17(a)(2) if, prior to export of the pesticide, the exporter submits to EPA a statement signed by the foreign purchaser which affirms that the purchaser is aware that the pesticide is not registered for use in the United States and cannot be sold for use in the United States. The exporter must also include with the submission of the purchaser acknowledgement statement to EPA, a certification signed by the exporter affirming that the export did not occur until the statement signed by the foreign purchaser was obtained by the exporter. Except as provided in paragraph (b) of this section, all pesticide products produced for export which cannot be sold for use in the United States in the form that they are produced for export, are considered to be unregistered pesticides. This includes pesticides which are of a different formulation, including composition (except for variation within certified limits), or type of formulation, and pesticides which are packaged for use patterns for which they are not registered, which may be evidenced by package type or label use statements. This also includes unregistered products which are under development as pesticidal products and which are being exported for research testing.

(b) *Exceptions.* Under the specific circumstances discussed below, EPA will not treat a registered product which has been modified slightly for export purposes, as unregistered for the purposes of the purchaser acknowledgement statement requirement. Any changes to the registered product for export purposes must be documented in accordance with the record-keeping requirements at § 169.2 of this chapter and this policy.

(1) *Labeling on Immediate Product.* EPA will not treat as unregistered for the purposes of section 17(a)(2), a registered pesticide product which cannot be sold or distributed for use in the United States because its immediate product container does not bear a label approved under a FIFRA section 3 registration, but which could be sold or distributed in the United States with the approved label attached to the immediate product container, provided that the label and labeling approved under a current FIFRA section 3 registration for the product is either attached to the immediate product container or accompanies the product at all times as supplemental labeling as provided in paragraph (c) of this section.

(2) *Packaging.* (i) Certain changes may be made to a product's labeling or packaging without affecting the registration status of the product, as specified in § 152.46(b) of this chapter and this policy. These changes include any changes in package size and label net contents, provided no change in use directions or requirement for child-resistant packaging would be necessary for the product to be registered for use in the United States. For example, if child-resistant packaging is required for a particular pesticide product in the United States, and the product will be exported without child-resistant packaging, the product would be considered unregistered and therefore subject to all the requirements of FIFRA section 17(a), as described in § 168.75 of this chapter including the requirement for a purchaser acknowledgement statement.

(ii) If an exporter needed to repackage a product in a size to meet a foreign purchaser's specifications, that modification would not affect the registration status of the export product. Other modifications to the label used for export purposes which will not affect the export product's registration status are: the use of metric units for net contents, dosages, and other numeric expressions; the use of a different format for the label, provided that the information does not contradict the U.S. label; revision of non-mandatory U.S. label statements, consistent with 40 CFR part 156, including additions or changes required by other Federal statutes or regulations; a change of the name or address of the registrant, except for a change resulting from transfer of ownership, which requires that a registrant keep his name and address current with the Agency; and any correction of typographical or printing errors that appeared on the U.S. labeling. (See § 152.46(b)).

(3) *Labeling statements.* The following statements which appear on any of the product labels or labeling will not affect the status of the product, provided that they do not contradict the approved FIFRA section 3 labeling:

(i) It is permissible to add explanatory language which accurately explains the meaning of a use classification. For example, the statement "restricted use pesticide" may be expanded to read: "Restricted in the United States of America to use by certified applicators" or "Restricted Use Pesticide. In The United States this product is restricted to use by applicators determined by each state to be competent in pesticide application and the human health and environmental consequences of misuse." If the explanatory language falsely represents or is misleading regarding the U.S. use classification, the product will be considered misbranded. In addition, a use classification can only be listed if one has been assigned pursuant to the U.S. registration.

(ii) An exporter who is also the manufacturer of a U.S. registered

pesticide may add new uses to the label of that product for export purposes, without triggering the requirements of section 17(a)(2), as long as the new uses are within the same general use patterns as those for the registered product. (Pesticide use patterns are listed in Appendix A to 40 CFR part 158-Data Requirements for Registration: Use Pattern Index. The general pesticide use patterns are: terrestrial food crop and terrestrial nonfood crop; greenhouse food crop and greenhouse nonfood crop; aquatic food crop and aquatic nonfood crop; indoor use; and forestry use.) Adding new uses to the label which change the use pattern, such as changes from non-food to food use, outdoor to indoor use, or terrestrial to aquatic use, render the product unregistered and subject to the requirements of section 17 for unregistered products. If the new use added to the label is a food or feed use, a tolerance must already be established for the use of that pesticide in or on that commodity.

(4) *Composition.* EPA will not treat a registered product as unregistered for the purposes of the purchaser acknowledgement statement requirement under the following specific circumstances:

(i) The formula of the exported product is within certified limits of the formula of the U.S. registered product.

(ii) An exporter, who is also the manufacturer of a U.S. registered pesticide, may decrease the percentage of the active ingredient(s) of that product by adding a List 4 inert ingredient, without causing the product to be treated as "unregistered" and triggering the requirement to obtain a purchaser acknowledgement statement as a condition for export. In EPA's Policy Statement on Inert Ingredients in Pesticide Products, EPA included inert ingredients on List 4-a list of inert ingredients posing minimal hazard or risk-if the inert ingredients were generally regarded as innocuous. The provisions of this paragraph do not apply to those pesticide products intended for public health uses which are required or conditionally required to submit efficacy data pursuant to § 158.640 of this chapter. Any differences in formula or composition caused by adding a List 4 inert must be reflected in records which show the complete formula of the export product in accordance with the requirements of § 169.2 and this policy.

(iii) A change in the color or fragrance of the export product will not affect the product's registration status as long as the following conditions are met. The change in color must result only from the addition of a dye included on the list of the chemicals exempted from the requirement of a tolerance at § 180.1001, and the dye must not be a List 1 inert. (List 1 inerts are those inerts which the Agency has identified as presenting toxicological concerns. The classification of inerts is explained in EPA's Policy Statement on Inert Ingredients in Pesticide Products. The change in fragrance must result only from the addition of a chemical included on the list of chemicals exempted from the requirement of a tolerance (§ 180.1001) and the chemical must not be a List 1 inert. The change in fragrance must not result in a pesticide product containing a food or food-like fragrance. (See "Food Fragrances in Pesticide Formulations," EPA's Office of Pesticide Programs Policy and Criteria Notice number 2155.1, November 20, 1975.) Any difference in color or fragrance of the export product in accordance with this section must be reflected in records which show the complete formula of the export product in accordance with the requirements of § 169.2 and this policy.

(5) *Research and development products.* An unregistered pesticide product exported only for research and development purposes is subject to the notification requirements of this section, unless its use fits within the criteria described in this paragraph.

(i) An unregistered pesticide product exported solely for research and development purposes will not be considered to be in violation of the notification requirements if the export of the research and development product:

(A) Would not involve land uses of more than 10 acres (4.05 hectares), or be used on or affect food or feed crops which are intended for consumption.

(B) Would not involve aquatic uses of more than 1 acre (0.405 hectares), or any aquatic uses which involve water used for irrigation, drinking or recreation, or be used on or affect plants or animals taken for food or feed from such waters.

(C) Would not involve tests on animals intended for food or feed.

(ii) Shipments to different purchasers, to different countries of final destination, or which occur more than a calendar year apart will be evaluated separately. When determining whether total shipments exceed the criteria described in this paragraph, EPA will evaluate the total amount of shipments by a single exporter during a calendar year for use in a particular country.

(iii) An exporter bears the burden of demonstrating that the product meets these criteria before the research product is shipped. This may be met by documenting before the product is shipped and maintaining records for the time period required by § 169.2(h) of this chapter from the date of the last shipment relevant to such records. The records to be maintained consist of:

(A) The identity of the purchaser and country of intended use of the research product.

(B) The amount shipped.

(C) The intended research use by the purchaser, including the type of application site, rate of application, and measures taken for protection of humans from direct or dietary exposure.

(c) *Procedures.* An exporter of an unregistered pesticide product must submit a purchaser acknowledgement statement to EPA containing the information stated in paragraph (c)(1) of this section, and a statement signed by the exporter certifying that the exportation did not occur until the signed acknowledgement statement had been obtained from the purchaser. If the foreign purchaser signs a purchaser acknowledgement statement in their own language, it must be accompanied by an English translation when it is submitted to EPA by the exporter. Those statements shall be submitted in accordance with one of the two options for submission described in paragraph (c)(2) of this section.

(1) *Contents of the purchaser acknowledgement statements.* The purchaser acknowledgement statement must include the following information in a format that is clearly understandable:

(i) Name, address, and EPA identification number, if applicable, of the exporter.

(ii) Name and address of the foreign purchaser.

(iii) Identity of the product and the active ingredient(s), including:

(A) The Chemical Abstract Services (CAS) Registry number for each active ingredient.

(B) The chemical nomenclature for each active ingredient as used by the International Union of Pure and Applied Chemists (IUPAC).

(C) Other known chemical or common names; or if the export involves a research product, a code name or identification number that can be used by EPA to identify the product from the exporter's records. If a code name or identification number is used, additional information must be attached to the certification statement submitted with the purchaser acknowledgement statement which will enable EPA to identify the product. This attached information may be claimed as confidential, and EPA will not forward this information with the purchaser

acknowledgement statement to foreign governments.

(iv) If known or reasonably ascertainable, the country or countries of final destination of the export shipment, i.e., where the exported pesticide is intended to be used, if different from the country of the foreign purchaser's address.

(v) A statement that indicates that the foreign purchaser understands that the product is not registered for use in the United States and cannot be sold in the United States.

(vi) The signature of the foreign purchaser.

(vii) The date of the foreign purchaser's signature.

(2) *Reporting options.* At the discretion of the exporter, the requirements of paragraph (c)(1) of this section may be met on a per-shipment or annual basis, as stated in paragraphs (c)(2)(i) and (c)(2)(ii) of this section. If the procedures in paragraph (c)(2)(ii) of this section are not followed, EPA will consider paragraph (c)(2)(i) of this section, requiring pershipment purchaser acknowledgement statements, to be applicable in full. Where paragraph (c)(2)(i) of this section is applicable, each shipment which does not meet the requirements of that paragraph will be considered to be a separate violation of FIFRA.

(i) *Per-shipment purchaser acknowledgment statement.* Unless the exporter chooses to follow the procedures described in paragraph (c)(2)(ii) of this section for the annual reporting procedures, the exporter must obtain and submit to EPA, a signed purchaser acknowledgement statement prior to each shipment of an unregistered pesticide according to the following procedures:

(A) Prior to each shipment in a calendar year of an unregistered pesticide product to a particular purchaser in a foreign country, the exporter must provide the foreign purchaser with instructions about the required information on a purchaser acknowledgement statement, and inform the foreign purchaser that the pesticide product cannot be exported from the United States until the exporter has received from the foreign purchaser a properly completed, signed, and dated acknowledgment statement.

(B) The exporter must obtain, prior to each shipment in a calendar year of an unregistered pesticide product to a particular purchaser in a foreign country, a signed purchaser acknowledgment statement which contains the information set forth in paragraph (c)(1) of this section.

(C) The exporter must sign a statement certifying that export did not take place until a signed purchaser acknowledgement statement was received. The exporter must also specify the chemical identity of any research product which is referred to by code in the purchaser acknowledgement statement. The information regarding the specific identity of research products, which may be included in the statement or consist of an attachment to the certification, may be claimed as confidential.

(D) The exporter must submit the signed acknowledgement statement from the foreign purchaser, and the accompanying certification by the exporter including attachments, to EPA within 7 working days of the exporter's receipt of the purchaser acknowledgement statement, or by the date of export, whichever occurs first. This information must be transmitted to the following address:
U.S. Environmental Protection Agency, Office of Pesticide Programs, (H–7501C), 401 M Street, SW, Washington, DC 20460, Attention: Purchaser Acknowledgement Statement.

(ii) *Annual reporting procedures.* Unless the exporter chooses to follow the per-shipment reporting option described in paragraph (c)(2)(i) of this section, the exporter must follow the procedures for annual summary reporting which include the requirement of a purchaser acknowledgement statement for the first shipment each calendar year of an unregistered pesticide product to a particular purchaser, and an annual summary of shipments to that purchaser. The annual summary reporting procedures are as follows:

(A) Prior to the first shipment each calendar year of an unregistered pesticide product to a particular purchaser in a foreign country, the exporter must provide the foreign purchaser with instructions about the required information on a purchaser acknowledgement statement, and inform the foreign purchaser that the pesticide product cannot be exported from the United States until the exporter has received from the foreign purchaser a properly completed, signed, and dated purchaser acknowledgement statement.

(B) The exporter must obtain, prior to the first shipment each calendar year of an unregistered pesticide product to a particular purchaser in a foreign country, a signed purchaser acknowledgement statement which contains the information set forth in paragraph (c)(1) of this section.

(C) The exporter must sign a statement certifying that export did not take place until a signed purchaser acknowledgement statement was received, indicating that this statement is for the first shipment to a particular purchaser in a specific country for that calendar year, and that the exporter will meet all the purchaser acknowledgement statement requirements as described in this paragraph (c)(2)(ii) of this section. The exporter must also specify the chemical identity of any research product which is referred to by code in the purchaser acknowledgement statement. The information regarding the specific identity of research products, which may be included in the statement or consist of an attachment to the certification, may be claimed as confidential.

(D) The exporter must submit the signed acknowledgement statement from the foreign purchaser, and the accompanying certification by the exporter including attachments, to EPA within 7 working days of the exporter's receipt of the purchaser acknowledgement statement, or by the date of export, whichever occurs first. This information must be transmitted to the following address:
U.S. Environmental Protection Agency, Office of Pesticide Programs, (H–7501C), 401 M Street, SW, Washington, DC 20460, Attention: Purchaser Acknowledgement Statement.

(E) The exporter, who has chosen to comply with the requirements of this paragraph instead of providing per-shipment purchaser acknowledgement statements in accordance with paragraph (c)(2)(i) of this section, must submit an annual summary report to EPA. An annual summary report is required for each unregistered pesticide exported within the preceding calendar year. The report must be in writing, signed by the exporter, and include the following information:

(*1*) Name, address, and EPA identification number if applicable, of the exporter.

(*2*) Name and address of the foreign purchaser, and the date the purchaser acknowledgement statement, submitted to EPA during the previous calendar year, was signed by the purchaser.

(*3*) The identity of the product and the active ingredients, including: the Chemical Abstract Services (CAS) registry number for each active ingredient, the chemical nomenclature for each active ingredient used by the International Union of Pure and Applied Chemists (IUPAC), and other known chemical or common names, or if the export involves a research product, the code name or identification number that can be used by EPA to

identify the product from the exporter's records.

(4) The dates of each shipment of the pesticide exported to the foreign purchaser during that calendar year.

(5) If known, or reasonably ascertainable, the country or countries of final destination of the export shipments, i.e., where the exported pesticide was intended to be used, if different from the foreign purchaser's address.

(F) The exporter shall submit the annual summary no later than March 1st of the following calendar year. The annual summary shall be sent to the following address:

U. S. Environmental Protection Agency, Office of Pesticide Programs, H-7501C, 401 M Street, SW., Washington, DC 20460, Attention: Annual Summary of Exports.

(iii) *Confidentiality claims.* Persons submitting the information specified in the purchaser acknowledgement statement may assert a claim of business confidentiality by marking the information claimed confidential as "FIFRA Confidential Business Information." Information so claimed will not be disclosed, with the exception of disclosure to the foreign governments, except in accordance with the procedures set forth in 40 CFR part 2, 7 U.S.C. 136(h), and this policy statement. If such claim is not asserted, EPA may disclose the information to the public without providing further notice prior to disclosure or an opportunity to object. Notwithstanding any claim of confidentiality, the purchaser acknowledgement statement will continue to be forwarded to the appropriate foreign government officials in its entirety, as required by section 17(a)(2).

(3) *Recordkeeping.* Except as specifically stated, the requirement to retain records under part 169 of this chapter applies to all pesticide producers, regardless of whether a particular product is intended for export. All records shall be maintained in accordance with the time period required by § 169.2(h) of this chapter. Producers must also maintain certain records pertaining to pesticide products intended for export. In addition to the requirement that a copy of the purchaser acknowledgement statement be kept, as stated at § 169.2(h)(3) of this chapter, the following records must be maintained:

(i) Copies of the instructions provided to foreign purchasers in accordance with paragraphs (c)(2)(i)(A) and (c)(2)(ii)(A) of this section.

(ii) Copies of signed purchaser acknowledgement statements obtained according to paragraphs (c)(2)(i)(B) and (c)(2)(ii)(B) of this section.

(iii) Copies of the certification from the exporter; and copies of any accompanying information regarding the identity of coded R&D products.

(d) *Agency transmission of purchaser acknowledgement statements.* EPA will transmit a copy of each purchaser acknowledgement statement to the appropriate government official in each of the intended destination countries. After receipt of the Annual Summary the following calendar year, EPA will also transmit a copy of that document to the appropriate government official in each of the intended destination countries. In the case that no Annual Summary has been received within 30 days of the date at which such summary is required to be submitted, EPA will send written notification to the appropriate government official indicating that no summary was submitted, and may also take enforcement action against the exporter.

§ 168.85 Other export requirements.

This section describes other requirements found in regulations that apply to exporters of pesticides, devices, and active ingredients used in producing a pesticide.

(a) *Recordkeeping and inspection.* Exporters of pesticides, devices and active ingredients must keep records and permit inspections of those records in accordance with part 169 of this chapter. Exporters must keep records of the product labeling used, including the EPA registered labeling, any foreign labeling on or attached to the product when shipped, and, as applicable, any supplemental labeling used. Producers of pesticides for export shall maintain these records in a manner that shows exactly which labels and labeling accompanied each shipment of a pesticide product to a foreign country. As stated at § 168.75(c), when research product identity information appears on the labeling in an encoded manner, information translating the code shall be maintained in records. These records shall be maintained for the time period required by § 169.2(h) of this chapter following the last export of such pesticides. All records required by part 169 of this chapter shall be made available for inspection and copying by EPA or its duly authorized representatives.

(b) *Pesticide production establishment requirements.* Exporters of pesticides, devices, and active ingredients must submit annual reports to EPA in accordance with part 167 of this chapter, concerning those products that are exported. All products required to be labeled "Not Registered for Use in the United States of America" must be reported as unregistered production regardless of whether a purchaser acknowledgement statement is required.

PART 169 [AMENDED]

2. In part 169

a. The authority citation for part 169 continues to read as follows:

Authority: 7 U.S.C. 136f and 136w.

b. Section 169.2 is amended by revising paragraph (h)(3) and the flush text that immediately follows paragraph (h)(3) to read as follows:

§ 169.2 Maintenance of records.

* * * * *

(h)* * *

(3) For any pesticide other than a pesticide registered under section 3 or sold under section 6(a)(1) of the Act, copies of a statement signed by the foreign purchaser of the pesticide acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under this Act.

These records shall be retained for a period of 2 years after expiration of the contract.

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